

# **CONFIDENTIAL DOCUMENT**

**Dona Libânia National Dermatological Reference Centre  
Fortaleza, CE**

***Independent study to evaluate the efficacy of the  
Six-dose uniform MDT regimen (U-MDT)  
for leprosy patients***

## **PATIENT CHART**

**General coordinator: Dr. Gerson Penna, MD, PhD**

### **Principal Researchers**

**Dr. Gerson Penna, MD, PhD  
Dr. Samira Bührrer-Sékula, PhD**

**Researchers at the Dona Libânia National Dermatological  
Reference Centre**

**Dr. Maria Araci Pontes  
Dr. Heitor de Sá Gonçalves**



**Dona Libânia National Dermatological Reference Centre Fortaleza (CE)**  
**INFORMED CONSENT FORM**

The study must be explained orally to children in a simple way allowing them to understand, as much as possible, what will happen in the study.

(1) Explanation of the Consent Form:

**Title of the study:** *"Independent study to establish the efficacy of the six-dose uniform MDT regimen (U-MDT) for leprosy patients"*.

**Principal investigators:**

Principal investigator: Dr. Gerson Oliveira Penna, Tropical Medicine Unit, University of Brasilia

Principal investigator at the Dona Libânia National Dermatological Reference Centre: Dr. Maria Araci Pontes

(2) Information regarding participation in the study:

**Institutions:** Tropical Medicine Unit, University of Brasilia  
Dona Libânia National Dermatological Reference Centre

You have been invited to participate in a medical research study. It is important for you to understand the general principles that will be applied to all participants of this study: (1) Your participation is voluntary. (2) You may decide to withdraw from the study before initiating treatment, or at any subsequent time. You will not be penalised or lose your right to treatment if you decide not to participate. (3) After reading this explanation, feel free to ask any questions you have to understand the study completely.

You are presenting symptoms that might be LEPROSY (HANSEN'S DISEASE), a curable disease that is treated with various types of medicines given at the same time. When leprosy is not treated, it can cause physical deformities. The study you are invited to be part of voluntarily is a clinical study that will attempt to better understand this disease, especially in relation to the length of time needed for treatment, because for some forms of the disease, the current treatment period is still very long.

Some researchers think that the length of treatment can be reduced without compromising patient cure. Read the information carefully before giving your consent. By signing this consent form you are agreeing to participate in the clinical research called: *"Independent study to establish the efficacy of the six dose uniform MDT regimen (U-MDT) for leprosy patients"*.

The objective of this study is to verify if one treatment regimen can be used for all leprosy patients, reducing the treatment to 6 months for those patients who at the present time are being treated for 12 months.

(3) Procedures to be followed:

If you agree to participate in this study, after signing the consent form, we will fill out your medical form, do a physical examination and run some laboratory tests so that we can determine the type of leprosy you have: (1) leprosy with few lesions (paucibacillary) or (2) leprosy with a greater number of lesions (multibacillary).

If you are classified as paucibacillary, you will participate in a random selection that will determine your participation in one of the 2 groups below:

Group 1 – you will use the one regimen treatment consisting of six-dose of three medications and annual follow-up for 5 years after the completion of treatment (U-MDT),

Or

Group 2 – you will use the same regimen as presently used, consisting of six-dose of two medications and annual follow-up for 5 years after the completion of treatment (R-MDT).

If you are classified as multibacillary, you will participate in a random selection that will determine your participation in one of the 2 groups below:

Group 3 – you will receive six-dose of three medications and monthly follow-up for 6 months and annual follow-up for 5 years after the completion of treatment (U-MDT),

Or

Group 4 - you will receive twelve doses of three medications and annual follow-up for 5 years after the completion of treatment (R-MDT).

The medication will be taken every day at home and once a month at the Health Centre. The oral medications used daily have been used for the treatment of leprosy for over 25 years.

We will also collect blood and take a small piece of your skin (biopsy) for examination. A picture of your lesion will be taken as well, at the beginning of the treatment, for comparison in the case of relapse. These tests are important for your participation in this study.

A sample of your blood will be collected and stored and will only be used if authorised by the lead investigator of the study.

All the samples will be labelled with the patient number and their initials so that confidentiality is guaranteed. If any new test or component is discovered that would benefit the participant, the researcher will access the lead investigator's file—the only place where patient data will be stored-- the patient will be contacted and informed about this benefit.

During the duration of your treatment, you will be examined monthly to monitor the treatment. After that, you will be examined once a year for five years, and after that your participation in the study will end.

If during the study you present any leprosy reactions or any other health problem, you should come to the Health Centre and inform the research team.

If you present symptoms of leprosy again, your physician may start a new treatment, following the recommendations of the Ministry of Health.

#### (4) Medications being researched

You will not be the first person to use the medications prescribed in this study, they have been in use for the successful treatment of leprosy for the last 20 years. Initially, they were used for periods of 5 years, then the treatment was reduced to 2 years and now they are used for 1 year. This study seeks to obtain information about the ideal treatment duration and determine if it is possible to treat all patients with only one treatment regimen for 6 months, instead of the current 12 months. We are going to evaluate the efficacy of shorter treatment by studying the possibility of relapse.

(5) Duration of your participation: 6 or 12 months of treatment and 5 years of follow-up.

(6) Risks, side effects and discomforts.

It is important for you to know that the risks involved with the treatment of leprosy are minimal. When not treated, it can cause physical deformities. Death as a result of leprosy is very rare.

The medications presently used in the standardised treatment of this disease (rifampicin, dapson and clofazimine) are the same that will be used in this study. Occasional side effects can include nausea, redness in urine, and one of the drugs can temporarily change skin colour. All these side effects will disappear once the treatment is over. It is important to take the medication everyday to obtain good results.

After the completion of the treatment, you should return to be examined at the Health Centre once a year for the next five years. It is important that you return for these visits so that we can be sure that the treatment duration is adequate. Independent of the course of treatment used, a small percentage of patients could relapse, and in this case, the patient will need to be treated again with the same multi-drug therapy as per Ministry of Health guidelines.

Only qualified health workers will administer treatment and examine the patients who voluntarily enrol in this study. They will observe you carefully to prevent any reaction and are prepared to treat you promptly, if necessary.

By participating in this study you will be contributing to the advancement of scientific knowledge about leprosy and as such you have certain responsibilities: follow closely the instructions given by your physician; come to the Health Centre on the dates scheduled; inform your doctor about any changes (good or bad) you notice during this study.

#### (7) Benefits.

The reduction of the treatment from 12 to 6 months for some patients and the possibility of having only one course for treatment for this disease will be of great benefit for all patients. Nevertheless, we cannot guarantee that this will be true for all patients.

In addition, you will be collaborating in a study that could benefit other people who may fall sick with the same disease.

The medical attention you receive is the principle benefit to you; there will be no monetary compensation for your participation in this study. At the same time, you will not incur any costs as a result of your participation. Given that you will often have to come to the Centre, you will receive bus vouchers to cover transportation costs for your visits.

#### (8) Identity confidentiality for the participants in this study.

The records of your participation in this study are confidential. However, these records will be available to the representatives of the institutions participating in the study, the Research Ethics Committees and health authorities. Your name will never be used in any study report.

#### (9) Your participation can be cancelled without your permission.

Your participation in this study can be interrupted if the state of your health begins to represent a risk to you in the opinion of the doctors responsible for this study.

#### (10) New significant findings.

Any important information that may become known during your participation in this study and that can affect your health will be given to you.

#### (11) Number of volunteers participating in this study.

A total of 2,122 patients will take part in this study, ranging from 5 to 65 years of age.

Patients with known allergies (hypersensitivity) to the drugs used in this study and patients with associated diseases will not be able to participate in this study.

(12) Reimbursement and Compensation.

If it is proven that you have suffered any injury as a result of your participation in this study, you will be entitled to medical treatment and reimbursement according to item V.6 of Resolution 196/96 of the National Health Council of the Ministry of Health that covers all medical research involving human subjects. This resolution establishes that: "Research subjects, when injured in any way by any protocol done by the research study, stated or not in the consent form, and as a result of his participation, will be entitled to complete medical assistance and legal compensation".

(13) People and places to obtain answers to questions and further information related to the study.

Please contact one of the persons listed below in case you have questions related to this study or if you have any problem:

Dr. Maria Araci de Andrade Pontes - telephones: 3101-5452 / 9981- 8124;

Dr. Heitor de Sá Gonçalves - telephones: 3101-5452 / 9988- 0777;

Address: Centro de Dermatologia D. Libânia

Rua Pedro I, 1033 - Centro

Fortaleza - Ceará

If any symptoms of the disease return, please come immediately to the Dona Libânia National Dermatological Reference Centre.

You can and should ask any questions you might find necessary before agreeing to participate in this study and at any moment during the treatment. Your doctor can give you all the information about your health, your rights, and possible complications and benefits related to your participation in this study. If you did not understand any part of this document or the explanation that was given to you, ask the physician before signing the consent form.

**IF YOU DID NOT UNDERSTAND ANY PART OF THIS DOCUMENT OR THE EXPLANATION THAT WAS GIVEN TO YOU, ASK THE PHYSICIAN BEFORE SIGNING THE CONSENT FORM.**

**RESEARCH SUBJECT OR LEGAL GUARDIAN'S (if subject is a minor < 15 yrs.)  
IDENTIFICATION DATA**

**1. PATIENT NAME:**

.....  
Sex: M ( ) F ( ) Date of birth: ...../...../..... Age: .....  
Address ..... N° .....  
District ..... City .....  
Postal code ..... Telephone: (.....).....

**2. LEGAL GUARDIAN**

Name.....  
Relation to the patient (relative, tutor, legal representative, etc).....  
Identity number ..... Sex: M ( ) F ( )  
Date of birth:...../...../.....  
Address ..... N° .....  
Apt.....  
District /Bairro.....  
City ..... Postal code ..... Tel: (.....).....

**3. ADDITIONAL INFORMATION**

Medical chart number in the Health Centre.....  
Main symptom.....  
BCG scars:      No scar,    1 scar,    2 scars  
History of current disease (HDA)  
How long have the symptoms been present: .....months  
Presently using any medication?    NO    YES   List of medications:  
.....  
.....  
Allergies: .....

**FREE AND INFORMED CONSENT FORM**

I, \_\_\_\_\_, of sound mind, am 18 years of age or older and volunteer  
(name of the volunteer)  
to participate in the study entitled ***"Independent study to establish the efficacy of the six dose uniform MDT regimen (U-MDT) for leprosy patients"***.

The implications of my voluntary participation, including the nature, duration and objective of this study, the methods and means of its conduction, as well as any problems and risks that might occur, were explained to me. I had the opportunity to clarify any doubts about the study and obtain explanations for those doubts. I voluntarily agree to participate in this study. I also understand that I can at any time withdraw my participation without punishment and retaining all my rights. My refusal to participate will not result in loss of any benefits I am otherwise entitled to. I will receive a copy of this statement and the consent form.

I \_\_\_\_\_ authorise the use of the blood and skin samples collected in this  
(Name of the volunteer)  
study for use in future studies.

\_\_\_\_\_  
Volunteer name

\_\_\_\_\_  
Signature or thumb print

\_\_\_\_\_  
Date and time of signature

**For illiterate volunteers:**

I was present during the explanation of the study, and can confirm that the volunteer was given the opportunity to ask questions and has given his/her signature above.

\_\_\_\_\_  
Witness name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date and time of signature

**Researcher declaration:**

The objective of the study was explained to the volunteer. To the best of my knowledge, he/she understood the objectives, procedures, risks and benefits of this study.

\_\_\_\_\_  
Name of the researcher

\_\_\_\_\_  
Signature of the researcher

\_\_\_\_\_  
Date and time of signature



**VOLUNTARY CONSENT FORM AND EXPLANATION FOR MINORS**

I, \_\_\_\_\_, of sound mind, am 18 years of age or older and  
(name of legal guardian)  
capable of giving consent for \_\_\_\_\_ and through this document,  
(name of minor)

I agree for him/her to volunteer as a participant of the study, ***“Independent study to establish the efficacy of the six-dose uniform MDT regimen (U-MDT) for leprosy patients”***.

The implications of his/her voluntary participation, including the nature, duration and objective of this study, the methods and means of its conduction, as well as any problems and risks that might occur, were explained to me. I had the opportunity to clarify any doubts about the study and obtain explanations to those doubts. I also understand that I can, at any time, withdraw my consent for the child under my responsibility to participate in this study, without any punishment to the child and retaining all his/her rights. I will receive a copy of this statement and the consent form.

I \_\_\_\_\_ authorise the use of the blood and skin samples collected from  
(Name of the volunteer)  
the minor under my responsibility in this study for use in future studies.

\_\_\_\_\_  
Name of legal guardian

\_\_\_\_\_  
Signature or thumb print

\_\_\_\_\_  
Date and time of signature

**For illiterate legal guardians:**

I was present during the explanation of the study, and can confirm that the volunteer was given the opportunity to ask questions and has given his/her signature above.

\_\_\_\_\_  
Witness name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date and time of signature

**Researcher declaration:**

The objective of the study was explained to the volunteer. As best as I can tell, he/she understood the objectives, procedures, risks and benefits of this study.

\_\_\_\_\_  
Name of the researcher

\_\_\_\_\_  
Signature of the researcher

\_\_\_\_\_  
Date and time of signature

## INDEX

	<b>Procedure timetable</b>	<b>12</b>
	<b>General Instructions</b>	<b>13</b>
	<b>Block I – Forms For Patient Data Collection upon Entry into the Study - 1st Dose</b>	<b>14</b>
<b>1</b>	<b>Instructions to initiate the study – 1st dose</b>	<b>15</b>
1.1	Criteria for inclusion/ exclusion from the study	16
1.2	Clinical and biopsy data from the patient	17
1.3	Clinical-dermatological evaluation	18
1.4	Examination of peripheral nerves	20
1.5	Simplified evaluation of neural function and complications	22
1.6	Request for laboratory exams	22
1.7	Results of laboratory tests – beginning of the study/1st dose	23
	<b>Instructions for monthly visits (months 2 to 12)</b>	<b>25</b>
<b>2</b>	<b>Block II – Monthly evaluation forms</b>	<b>26</b>
2.1	Clinical-dermatological evaluation – 2nd dose	27
2.2	Examination of peripheral nerves – 2nd dose	28
2.3	Request for laboratory exams	28
2.4	Clinical-dermatological evaluation – 3rd dose	29
2.5	Examination of peripheral nerves - 3rd dose	30
2.6	Request for laboratory exams	30
2.7	Clinical-dermatological evaluation – 4th dose	31
2.8	Examination of peripheral nerves - 4th dose	32
2.9	Request for laboratory exams	32
2.10	Clinical-dermatological evaluation – 5th dose	33
2.11	Examination of peripheral nerves – 5th dose	34
2.12	Request for laboratory exams	34
2.13	Clinical-dermatological evaluation – 6th dose	35
2.14	Examination of peripheral nerves - 6th dose	36
2.15	Request for laboratory exams	36
2.16	Simplified evaluation of neural function and complications	37
2.17	Clinical-dermatological evaluation – 7th dose	39
2.18	Examination of peripheral nerves – 7th dose	40
2.19	Request for laboratory exams	40
2.20	Clinical-dermatological evaluation – 8th dose	41
2.21	Examination of peripheral nerves – 8th dose	42
2.22	Request for laboratory exams	42
2.23	Clinical-dermatological evaluation – 9th dose	43
2.24	Examination of peripheral nerves – 9th dose	44
2.25	Request for laboratory exams	44

2.26	Clinical-dermatological evaluation – 10th dose	45
2.27	Examination of peripheral nerves – 10th dose	46
2.28	Request for laboratory exams	46
2.29	Clinical-dermatological evaluation – 11th dose	47
2.30	Examination of peripheral nerves – 11th dose	48
2.31	Request for laboratory exams	48
2.32	Clinical-dermatological evaluation – 12th dose	49
2.33	Examination of peripheral nerves – 12th dose	50
2.34	Request for laboratory exams	50
	<b>Instructions for the end of the treatment - month 7 (PB) and 13 (MB)</b>	<b>51</b>
<b>3</b>	<b>Block III – Evaluation forms for the end of treatment</b>	<b>52</b>
3.1	Clinical-dermatological evaluation – End of treatment	53
3.2	Examination of peripheral nerves - End of treatment	54
3.3	Simplified evaluation of neural function and complications - End of treatment	55
3.4	Request for laboratory exams	57
	<b>Instructions for annual visits (Years 1 to 6)</b>	<b>58</b>
	<b>Summary of the annual visits</b>	<b>59</b>
<b>4</b>	<b>Block IV – Forms for annual follow-up visits</b>	<b>60</b>
4.1	Clinical-dermatological evaluation – 1st year	61
4.2	Examination of peripheral nerves - 1st year	62
4.3	Request for laboratory exams	62
4.4	Simplified evaluation of neural function and complications - 1st year	63
4.5	Clinical-dermatological evaluation – 2nd year	65
4.6	Examination of peripheral nerves – 2nd year	66
4.7	Request for laboratory exams	66
4.8	Simplified evaluation of neural function and complications – 2nd year	67
4.9	Clinical-dermatological evaluation – 3rd year	69
4.10	Examination of peripheral nerves – 3rd year	70
4.11	Request for laboratory exams	70
4.12	Simplified evaluation of neural function and complications – 3rd year	71
4.13	Clinical-dermatological evaluation – 4th year	73
4.14	Examination of peripheral nerves – 4th year	74
4.15	Request for laboratory exams	74
4.16	Simplified evaluation of neural function and complications – 4th year	76
4.17	Clinical-dermatological evaluation – 5th year	77
4.18	Examination of peripheral nerves – 5th year	78
4.19	Request for laboratory exams	78
4.20	Simplified evaluation of neural function and complications – 5th year	79
4.21	Clinical-dermatological evaluation – 6th year	81
4.22	Examination of peripheral nerves – 6th year	82

4.23	Request for laboratory exams	82
4.24	Simplified evaluation of neural function and complications – 6th year	83
<b>5</b>	<b>Block V – Miscellaneous forms</b>	<b>85</b>
5.1	Form for the diagnosis and follow-up of leprosy reactions	86-117
5.2	Bacilloscopy test results	118
5.3	Sulfonuria test results	119
5.4	Protein C reactive results - Monthly	120
5.5	Protein C reactive results - Annual	121
5.6	Protein C reactive results - during reactive periods	122
5.7	Registration of researched dose	123
5.8	Registration of use of other medications	124
5.9	Registration of adverse side effects	125
5.10.	Comments about eventual serious side effects	126
5.11	Relapse	
5.11.1	Clinical dermatological evaluation – relapse	127
5.11.2	Examination of peripheral nerves – relapse	128
5.11.3	Request for laboratory tests - relapse	128
5.11.4	Simplified evaluation of neural function and complications - relapse	129
5.11.5	Relapse registration	131
5.11.6	Biopsy – relapse	132
5.12	Form for withdrawal from the study	133

## PROCEDURE TIMETABLE

Evaluation	Initial visit	Monthly visits	Final visit 7th and 13th months	Visits during annual follow-up	In case of Leprosy Reactions
Clinical-dermatological evaluation	x	x	x	x	--
Examination of peripheral nerves	x	x	x	x	x
Classification of disabilities	x	--	x	x	--
Bacilloscopy <sup>1</sup>	x	--	x	x	--
Biopsy <sup>2</sup>	x	--	--	--	--
ML FLOW <sup>3</sup>	x	--	--	--	--
Complete blood exam <sup>4</sup>	x	x	x	--	--
Biochemistry	x	x	x		--
C reactive protein	x	x	x	x	x
SGOT, SGPT <sup>4</sup>	x	x	x		--
Registration of the supervised dose during the study	x	x	x	x	--
Side effects	x	x	x	x	x
Use of concurrent medications	x	x	x	x	x
Sulfonuria <sup>5</sup>	--	x	--	--	--

- (1) Bacilloscopy will be performed in all patients during the initial phase of the study, and at the end of the treatment and during the annual follow-up in the patients with multibacillary disease
- (2) The biopsy will be performed in all patients during the initial phase of the study and in case of suspected relapse
- (3) The ML-Flow test will be performed in all patients during the initial phase of the study and in case of suspected relapse.
- (4) Complete blood exam and SGOT/SGPT will be performed in all patients at all the monthly visits while the patient is taking MDT.
- (5) Every month there will be a random selection of 10% of all patients to determine which will have the sulfonuria test performed, as proof of the regular intake of the self-administered medications. The patients will not be informed beforehand about the fact that this exam indicates “regularity” of treatment

## General Instructions Form

1. This patient research file contains one copy of the forms to be utilised for each visit during the study: forms for the commencement of the study, clinical visits (Months 2 to 12), annual follow-up visits (Years 1 to 6), and final study visit. Forms are also provided to record: bacilloscopy, the C reactive protein (beginning of the study, months 2 to 12, years 1 to 6), the supervised research dose, concurrent medications, side effects, comments about serious side effects, withdrawal from the study, follow-up of reaction episodes and of relapse.
2. In the case that additional forms are needed (e.g. for multiple side effects, etc) please include the appropriate alphabetical letter after the page number. For example, the first form for Side Effects should come as “Page 17 A”; the second form as “Page 17 B”, etc.
3. Utilize **black** ink pen and write **legibly**.
4. All items should be filled out. The following abbreviations must be used when values or answers are not obtained:  
  
ND – Not done  
NA – Not applicable
5. The forms should be signed and dated by the researcher in the appropriate spaces.
6. In case a mistake occurs, draw a horizontal line across the item to be corrected in a way that it is still possible to read. Do not tear the form, use correction fluid or erase it. After each correction, number the alteration, date it and sign your initials.

# BLOCK 1

## FORMS FOR PATIENT DATA COLLECTION AT ENTRY INTO THE STUDY 1st DOSE

## **INSTRUCTIONS FOR PATIENT DATA COLLECTION AT ENTRY INTO THE STUDY – 1st DOSE**

- 1. Review the inclusion and exclusion criteria to verify the eligibility of the patient
  - a. Obtain demographic information.
  - b. Verify the diagnosis of leprosy and the date treatment commenced.
  - c. Evaluate the cutaneous lesions and/or systemic symptoms.
  - d. Review the patient history of previous treatments, and confirm enrolment in study.
  - e. Verify history of intolerance to any of the medications.
- 2. Inform the patient about the risks and benefits of the study. Complete the informed consent form, signed by the patient and by a witness in case the patient is illiterate. Give a copy to the patient and keep one copy in the study files.
- 3. If the patient is qualified to enter the study and has signed the Consent Form, begin filling the CRF in the sequence of the study.
- 4. Classify the disease as paucibacillary (PB) or multibacillary (MB), according to the WHO norms, using ONLY the number of skin lesions.
- 5. The tests and procedures listed below must be conducted at the beginning of the study. (Treatment can be initiated before obtaining the results) If the tests have already been done, enter the results in the CRF; otherwise, begin examinations.
  - a. Do the Clinical-dermatological evaluation.
  - b. Do the neurological examination; nerves must be palpated and evaluated for sensitivity and thickness.
  - c. Classify the disability grade according to the norms of WHO/Brazilian Ministry of Health.
  - d. Obtain blood for laboratory tests (full haemogram including differentials, biochemical tests (taken while fasting), C reactive protein) and undertake lymph bacilloscopy. File the results in the patient's chart and enter them in the form for Laboratory Exam Results.
  - e. Obtain the biopsy and request the histopathology exam.
  - f. Proceed with the ML Flow test and attach test results at the appropriate place.
- 6. Verify the treatment group for this patient on the randomisation table.
- 7. Give the medication under study to the patient. Register the number of pills given, using the Form for Registration of the Experimental Dosage, and record the lot number and the expiration date.
- 8. The researcher should check all the data registered on the Visit Form - Study Commencement and sign it at the bottom of the page.



PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

## 1. CRITERIA FOR INCLUSION/ EXCLUSION FROM THE STUDY

INCLUSION CRITERIA			
1. Five (05) to sixty-five (65) years of age	<input type="checkbox"/>	1. Yes	2. No    3. NA
2. Leprosy with characteristic skin lesions, with or without systemic symptoms or confirmed by histopathological study	<input type="checkbox"/>	1. Yes	2. No    3. NA
3. Never treated or patient treated more than five years ago	<input type="checkbox"/>	1. Yes	2. No    3. NA
4. Signed consent form.	<input type="checkbox"/>	1. Yes	2. No    3. NA

NA – Not applicable

\_\_\_\_\_  
 /   /  
 Date Signature

EXCLUSION CRITERIA			
1. Absence of leprosy skin lesions	<input type="checkbox"/>	1. Yes	2. No    3. NA
2. Pure neural leprosy (PNL)	<input type="checkbox"/>	1. Yes	2. No    3. NA
3. Patient at risk of death	<input type="checkbox"/>	1. Yes	2. No    3. NA
4. Patient previously treated for leprosy less than 5 years ago	<input type="checkbox"/>	1. Yes	2. No    3. NA
5. History of intolerance to one of the medications	<input type="checkbox"/>	1. Yes	2. No    3. NA
6. Discharged as a result of the histopathological findings.	<input type="checkbox"/>	1. Yes	2. No    3. NA
7. Association with other serious diseases such as HIV/AIDS, Tuberculosis, Malaria, LTA, Visceral Leishmaniasis, Lymphoma, Leukaemia, Immunosuppression, etc.	<input type="checkbox"/>	1. Yes	2. No    3. NA
8. Patient with difficulty following the procedures of the study	<input type="checkbox"/>	1. Yes	2. No    3. NA

NA – Not applicable

\_\_\_\_\_  
 /   /  
 Date Signature



PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

### 3 - CLINICAL- DERMATOLOGICAL EVALUATION

#### Beginning of the study – 1st dose

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Baseline of symptoms and signs to be studied	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Have any signs/symptoms of leprosy reactions?	1 – Yes    If yes, fill out the form for reactions in block V, <b>for each new episode</b> 2 – No
<input type="checkbox"/> Other (specify)	

\_\_\_\_\_  
Signature and stamp of medical examiner

## 4 - EXAMINATION OF PERIPHERAL NERVES

### Beginning of the study – 1st dose

	KEY NERVE EXAMINATION 0- Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF NEURAL PAIN INDICATED 0. No pain 1. Weak pain 2. Strong pain	
NERVES	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner




PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

### 5. SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS Beginning of the study – 1st dose





<b>Face</b>		
<b>Nose</b>	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>	<b>R</b>	<b>L</b>
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>	<b>R</b>	<b>L</b>
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
<p>key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours  <b>Mobile claw: M</b>; <b>rigid claw: R</b>; bone absorption:  wound: </p>	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular	R	L
Posterior tibial		



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels ✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

#### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**7. REQUEST FOR LABORATORY EXAMS**  
**Beginning of the study – 1st dose**

<input type="checkbox"/>	BIOCHEMISTRY (urea, creatinine, SGOT, SGPT, alkaline phosphatase, bilirubin, Fasting plasma glucose )
<input type="checkbox"/>	FULL HAEMOGRAM AND SEDATION RATE
<input type="checkbox"/>	BACILLOSCOPY
<input type="checkbox"/>	C- REACTIVE PROTEIN
<input type="checkbox"/>	ML-FLOW

OBS:

---



---



---



---



---

Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**8. LABORATORY RESULTS**  
Beginning of the study – 1st dose

<b>BIOCHEMISTRY</b>					
<b>TEST</b>	<b>Results</b>	<b>Normal values</b>	<b>units</b>	<b>Clinically significant ("✓")</b>	<b>COMMENTS</b> If test was not done, write ND
GLUCOSE		70 -110	mg/dl		
UREA		10 - 50	mg/dl		
CREATININE		0,4 – 1,3	mg/dl		
SGPT		4 – 32	U/L		
SGOT		4 – 36	U/L		
ALKALINE PHOSPH.		A – 13 – 43 C – 56 - 156	U/L		
TOTAL BILIRRUBIN		Up to 1,2	mg/dl		
C-REACTIVE PROTEIN		Less than 8	mg/L	<b>Results to be recorded in block V, page 120</b>	

<b>FULL BLOOD EXAM</b>					
<b>TEST</b>	<b>Results</b>	<b>Normal values</b>	<b>units</b>	<b>Clinically significant ("✓")</b>	<b>COMMENTS</b> If test was not done, write ND
RED BLOOD CELLS		4,0 - 5,5	tera/l		
HB		11 - 16	g/dl		
HCT		36 - 52	%		
MCV		82 - 92	fl		
MCH		27 - 31	pg		
MCHC		32 - 36	g/dl		

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

FULL BLOOD EXAM (continuation)					
TEST	Results	Normal values	Units	Clinically significant ("✓")	COMMENTS If test was not done, write ND
RDW		12 - 15	%		
PLATELETS		150000 - 450000	μL		
LEUKÓCYTES		4000 - 10000	μL		
%SEG		54 - 65	%		
% BAST		3-5	%		
% NEUTRO		40 - 75	%		
%LYMPH		23 - 35	%		
%MONO		3 - 8	%		
%EOS		1 - 4	%		
%BASO		0 - 1	%		
#SEG		2750 - 6500	μL		
#BAST		150-500	μL		
#NEUTRO		2500 - 7500	ml		
#LYMPH		1150 - 3500	μL		
#MONO		200 - 800	μL		
#EOS		50 - 400	μL		
#BASO		0 - 100	μL		

---

Signature and stamp of medical examiner

# BLOCK II

## Monthly Evaluations Forms

## INSTRUCTIONS FOR MONTHLY VISITS (MONTHS 2 to 12)

1. The following tests and procedures should be done during the monthly visits:
  - a. Do the Clinical-dermatological evaluation - months 2 through 6 for groups 1 and 2 of PB and months 2 through 12 for groups 3 and 4 of MB.
  - b. Perform the neurological exam that focuses on the detection of neuropathies. Nerves should be palpated and evaluated according to thickness and sensitivity. Record on the patient chart: examination of peripheral nerves.
  - c. Ask the patient about symptoms of leprosy reactions and evaluate the degree for each one of them. Register on the patient chart in the Diagnosis and Follow-up of Reactions Form.
  - d. Ask the patient about side effects and register them in the Clinical-Dermatological Evaluation Form
  - e. Enter the results for the C-reactive protein test.
  - f. Register the results of the sulfonuria test.
  - g. In case of the onset of a leprosy reaction, classify the disability level according to the norms of the Brazilian Ministry of Health and the World Health Organisation. Register this on the Diagnosis and Follow-up of Reactions Form.
2. Register the other medications being used concomitantly in the Use of Concurrent Medications Form, located in Block V.
3. Give the medication under study to the patient: doses 2 to 6 for groups 1 and 2 of PB and group 3 of MB; and doses 2 to 12 for group 4 of MB. Register the number of capsules given on the Form for Registration of Dose under Study, as well as the lot number and the expiration date of the medication.
4. The principal researcher should review all the recorded data in the Visit Forms during the study and sign them at the bottom of the page

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**CLINICAL-DERMATOLOGICAL EVALUATION - 2<sup>nd</sup> DOSE**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b>
	2 – No
	3—Continued symptoms of previous reaction

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES - 2nd DOSE**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**LABORATORY TEST REQUEST – 2<sup>nd</sup> dose**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**CLINICAL-DERMATOLOGICAL EVALUATION – 3<sup>rd</sup> DOSE**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b> 2 – No 3—Continued symptoms of previous reaction
---	--

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.

PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES - 3<sup>rd</sup> DOSE**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**LABORATORY TEST REQUEST – 3<sup>rd</sup> dose**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**CLINICAL-DERMATOLOGICAL EVALUATION – 4<sup>th</sup> DOSE**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b>
	2 – No
	3—Continued symptoms of previous reaction

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.



PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

### EXAMINATION OF PERIPHERAL NERVES – 4<sup>th</sup> DOSE

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

### LABORATORY TEST REQUEST – 4<sup>th</sup> dose

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

### CLINICAL-DERMATOLOGICAL EVALUATION – 5<sup>th</sup> DOSE

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b> 2 – No 3—Continued symptoms of previous reaction
---	--

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.

PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES – 5<sup>th</sup> DOSE**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**LABORATORY TEST REQUEST – 5<sup>th</sup> dose**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**CLINICAL-DERMATOLOGICAL EVALUATION – 6<sup>th</sup> DOSE**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b> 2 – No 3—Continued symptoms of previous reaction
---	--

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.

PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES – 6<sup>th</sup> DOSE**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**LABORATORY TEST REQUEST – 5<sup>th</sup> dose**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner




PATIENT INITIALS						PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS**  
**7th DOSE (MB - group 4) and 1st month after U-MDT (MB – group 3)**





<b>Face</b>				
<b>Nose</b>			<b>R</b>	<b>L</b>
Main complaint				
dryness (S/N)				
abrasions (S/N)				
Perforation of the septum (S/N)				
<b>Eyes</b>			<b>R</b>	<b>L</b>
Main complaint				
Closes eyes w/o force (mm)				
Closes eyes w/ force (mm)				
Cornea diminished sensibility (S/N)				
Cornea opacity (S/N)				
Cataract (S/N)				
Visual acuity				

<b>Upper limbs</b>				
Main complaint				
<b>Nerve palpation</b>			<b>R</b>	<b>L</b>
Ulnar				
Median				
Radius				

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger			
Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb			
Abduction of the thumb (median nerve)			
Elevates wrist			
Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours	
Mobile claw: <b>M</b> ; rigid claw: <b>R</b> ; bone absorption:  wound: 	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			
PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular	<b>R</b>	<b>L</b>
Posterior tibial		



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

#### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**CLINICAL DERMATOLOGICAL EVALUATION**  
**7th DOSE (MB - group 4) and 1st month after U-MDT (MB – group 3)**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/>	Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b>
		2 – No
		3—Continued symptoms of previous reaction

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.



PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES -  
7th DOSE (MB - group 4) and 1st month after U-MDT (MB – group 3)**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**LABORATORY TEST REQUEST  
7th DOSE (MB - group 4) and 1st month after U-MDT (MB – group 3)**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**CLINICAL DERMATOLOGICAL EVALUATION**  
**8th DOSE (MB - group 4) and 2nd month after U-MDT (MB – group 3)**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b>
	2 – No
	3—Continued symptoms of previous reaction

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES –  
8th DOSE (MB - group 4) and 2<sup>nd</sup> month after U-MDT (MB – group 3)**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**REQUEST OF LABORATORY EXAMS  
8th DOSE (MB - group 4) and 2nd month after U-MDT (MB – group 3)**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**CLINICAL DERMATOLOGICAL EXAMINATION**  
**9th DOSE (MB - group 4) and 3rd month after U-MDT (MB – group 3)**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/>	Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b>
		2 – No
		3—Continued symptoms of previous reaction

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**

**9th DOSE (MB - group 4) and 3rd month after U-MDT (MB – group 3)**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**REQUEST OF LABORATORY EXAMS**

**9th DOSE (MB - group 4) and 3rd month after U-MDT (MB – group 3)**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**CLINICAL DERMATOLOGICAL EXAMINATION**  
**10th DOSE (MB - group 4) and 4<sup>th</sup> month after U-MDT (MB – group 3)**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/>	Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b>
		2 – No
		3—Continued symptoms of previous reaction

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**

**10th DOSE (MB - group 4) and 4th month after U-MDT (MB – group 3)**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**REQUEST OF LABORATORY EXAMS**

**10th DOSE (MB - group 4) and 4th month after U-MDT (MB – group 3)**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**CLINICAL DERMATOLOGICAL EXAMINATION**  
**11th DOSE (MB - group 4) and 5th month after U-MDT (MB – group 3)**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/>	Have any signs/symptoms of leprosy reaction?	1 – Yes In this case, fill out the form for reactions in block V, for each new episode*
		2 – No
		3—Continued symptoms of previous reaction

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.



PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**

**11th DOSE (MB - group 4) and 5th month after U-MDT (MB – group 3)**

	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
NERVES	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**REQUEST OF LABORATORY EXAMS**

**11th DOSE (MB - group 4) and 5th month after U-MDT (MB – group 3)**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**CLINICAL DERMATOLOGICAL EVALUATION**  
**12nd DOSE (MB - group 4) and 6th month after U-MDT (MB – group 3)**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/>	Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b>
		2 – No
		3—Continued symptoms of previous reaction

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.

## EXAMINATION OF PERIPHERAL NERVES

**12th DOSE (MB - group 4) and 6th month after U-MDT (MB – group 3)**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

## REQUEST OF LABORATORY EXAMS

**12th DOSE (MB - group 4) and 6th month after U-MDT (MB – group 3)**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 120)
<input type="checkbox"/>	FULL BLOOD EXAM
<input type="checkbox"/>	SGOT / SGPT

OBS:

---



---



---

\_\_\_\_\_  
Signature and stamp of medical examiner

## **INSTRUCTIONS FOR COMPLETION OF TREATMENT (MONTH 7 – GROUPS 1 AND 2 [PB]; MONTH 13 – GROUP 3 AND 4 [MB])**

1. The following tests and procedures should be done during the monthly visits:
  - a. Complete the clinical-dermatological examination.
  - b. Perform the neurological examination; nerves must be palpated and evaluated for sensitivity and thickness. Register information on the Examination of Peripheral Nerves Form.
  - c. Ask the patient about symptoms of leprosy reactions and evaluate the severity for each of them. Enter data on the Reaction Follow-up Form.
  - d. Record the C - Reactive Protein results.
  - f. Enter bacilloscopy results.
  - g. Classify the disability grade according to the guidelines of the Brazilian Ministry of Health and the WHO
2. Register other medications in use by the patient in the Concurrent Medications Form.
3. The principal researcher should review all the data recorded on the Visit Forms during the study and sign them at the bottom of the page.

# BLOCK III

## Evaluation forms used at treatment completion

PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

### CLINICAL DERMATOLOGICAL EVALUATION - End of treatment

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Have any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b> 2 – No 3—Continued symptoms of previous reaction
---	--

\_\_\_\_\_  
Signature and stamp of medical examiner

\*In this study, a new episode of leprosy reaction is defined as when the patient develops new signs and symptoms of a reaction after a period of regression of the initial symptoms. It can happen during gradual reduction of the anti-reaction steroid therapy and requires a new intervention including adjustment of the medication dose.

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**  
**End of Treatment**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
 Signature and stamp of medical examiner




PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS**  
**End of Treatment**



<b>Face</b>		
<b>Nose</b>		
	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>		
	<b>R</b>	<b>L</b>
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>		
	<b>R</b>	<b>L</b>
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed

<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours <b>Mobile claw: M; rigid claw: R; bone absorption: ☒ wound: ☉</b>	



\_\_\_\_\_  
Signature and stamp of medical examiner





PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular	R	L
Posterior tibial		



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels ✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

#### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**REQUEST FOR LABORATORY EXAMS  
End of Treatment**

<input type="checkbox"/>	BACILLOSCOPY (for all MB patients and those PB patients with positive bacilloscopy at the beginning of the study (Record results in Block V, page 119)
<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 121)
<input type="checkbox"/>	FULL BLOOD EXAM

OBS:

---



---



---



---



---

Signature and stamp of medical examiner

## INSTRUCTIONS FOR ANNUAL VISITS (YEARS 1 to 6)

1. The following tests and procedures should be done at the time of the annual visits:
  - a. Complete the clinical-dermatological examination.
  - b. Do the neurological examination; nerves must be palpated and evaluated for sensitivity and thickness. Register information on the Examination of Peripheral Nerves Form.
  - c. Ask the patient about symptoms of leprosy reactions and evaluate the severity for each of them. Enter data on the Reaction Follow-up Form.
  - d. Histopathological exam to evaluate leprosy evolution of the paucibacillary patients.
  - e. Record the C - Reactive Protein results.
  - f. Enter bacilloscopy results.
  - g. Classify the disability grade according to the guidelines of the Brazilian Ministry of Health and the WHO.
2. Register other medications in use by the patient in the Concurrent Medications Form. This form is supplied in a separate section under Concurrent Medication Registry.
3. The principal researcher should review all the data recorded on the Visit Forms during the study and sign them at the bottom of the page.

## SUMMARY OF THE ANNUAL VISITS

- 1st year follow-up visit performed on ...../...../.....
- 2nd year follow-up visit performed on...../...../.....
- 3rd year follow-up visit performed on...../...../.....
- 4th year follow-up visit performed on...../...../.....
- 5th year follow-up visit performed on...../...../.....
- 6th year follow-up visit performed on...../...../.....

# BLOCK IV

## Forms for annual follow-up visits

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**CLINICAL DERMATOLOGICAL EVALUATION**  
**1st year follow-up**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Any signs/symptoms of leprosy reaction?	1 – Yes In this case, fill out the form for reactions in block V, <b>for each new episode*</b> 2 – No 3—Continued symptoms of previous reaction
<input type="checkbox"/> Any signs/symptoms of relapse?	1 – Yes In this case, fill out the relapse form in block V, <b>page 137*</b> 2 – No

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**EXAMINATION OF PERIPHERAL NERVES**  
**1st year follow-up**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

**REQUEST FOR LABORATORY EXAMS**  
**1st year follow-up**

<input type="checkbox"/>	BACILLOSCOPY (Register results in Block V, page 119)
<input type="checkbox"/>	C-REACTIVE PROTEIN (Register results in Block V, page 122)

OBS:

---



---

\_\_\_\_\_  
Signature and stamp of medical examiner




PATIENT INITIALS						PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

## SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS 1st year follow-up





<b>Face</b>		
<b>Nose</b>	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>	<b>R</b>	<b>L</b>
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>	<b>R</b>	<b>L</b>
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger			
Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb			
Abduction of the thumb (median nerve)			
Elevates wrist			
Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed

<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
<p>key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours</p> <p><b>Mobile claw: M</b>; <b>rigid claw: R</b>; bone absorption:  wound: </p>	



\_\_\_\_\_  
Signature and stamp of medical examiner





PATIENT INITIALS						PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular	R	L
Posterior tibial		



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

#### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**CLINICAL DERMATOLOGICAL EVALUATION**  
**2<sup>nd</sup> year follow-up**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Any signs/symptoms of leprosy reaction?	1 – Yes In this case, fill out the form for reactions in block V, <b>for each new episode*</b> 2 – No 3—Continued symptoms of previous reaction
<input type="checkbox"/> Any signs/symptoms of relapse?	1 – Yes In this case, fill out the relapse form in block V, <b>page 137*</b> 2 – No

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**EXAMINATION OF PERIPHERAL NERVES**  
**2<sup>nd</sup> year follow-up**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

**REQUEST FOR LABORATORY EXAMS**  
**2<sup>nd</sup> year follow-up**

<input type="checkbox"/>	BACILLOSCOPY (Register results in Block V, page 119)
<input type="checkbox"/>	C-REACTIVE PROTEIN (Register results in Block V, page 122)

OBS:

---



---




\_\_\_\_\_  
Signature and stamp of medical examiner

## SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS 2<sup>nd</sup> year follow-up





<b>Face</b>		
<b>Nose</b>	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>	<b>R</b>	<b>L</b>
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
<b>Nerve palpation</b>	<b>R</b>	<b>L</b>
Main complaint		
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed

<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
<p>key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours  <b>Mobile claw: M</b>; <b>rigid claw: R</b>; bone absorption:  wound: </p>	



\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--



### Classification of disability grade

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular		<b>R</b>
Posterior tibial		<b>L</b>



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation			
Elevates hallux			
Hallux extension (fibular nerve)			
Elevate foot			
Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**CLINICAL DERMATOLOGICAL EVALUATION**  
**3<sup>rd</sup> year follow-up**

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b> 2 – No 3—Continued symptoms of previous reaction
<input type="checkbox"/> Any signs/symptoms of relapse?	1 – Yes    In this case, fill out the relapse form in block V, <b>page 137*</b> 2 – No

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**  
**3<sup>rd</sup> year follow-up**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

**REQUEST FOR LABORATORY EXAMS**  
**3<sup>rd</sup> year follow-up**

<input type="checkbox"/>	BACILLOSCOPY (Register results in Block V, page 119)
<input type="checkbox"/>	C-REACTIVE PROTEIN (Register results in Block V, page 122)

OBS:

---



---



---

\_\_\_\_\_  
Signature and stamp of medical examiner




PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS**  
3rd year follow-up





<b>Face</b>				
<b>Nose</b>			<b>R</b>	<b>L</b>
Main complaint				
dryness (S/N)				
abrasions (S/N)				
Perforation of the septum (S/N)				
<b>Eyes</b>			<b>R</b>	<b>L</b>
Main complaint				
Closes eyes w/o force (mm)				
Closes eyes w/ force (mm)				
Cornea diminished sensibility (S/N)				
Cornea opacity (S/N)				
Cataract (S/N)				
Visual acuity				

<b>Upper limbs</b>				
Main complaint				
<b>Nerve palpation</b>			<b>R</b>	<b>L</b>
Ulnar				
Median				
Radius				

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed

<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours	
Mobile claw: <b>M</b> ; rigid claw: <b>R</b> ; bone absorption:  wound: 	



\_\_\_\_\_  
Signature and stamp of medical examiner





PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular	R	L
Posterior tibial		



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

#### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

### CLINICAL DERMATOLOGICAL EVALUATION - 4th year follow-up

Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				

Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				

<input type="checkbox"/> Any signs/symptoms of leprosy reaction?	1 – Yes In this case, fill out the form for reactions in block V, <b>for each new episode*</b> 2 – No 3—Continued symptoms of previous reaction
<input type="checkbox"/> Any signs/symptoms of relapse?	1 – Yes In this case, fill out the relapse form in block V, <b>page 137*</b> 2 – No

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**  
**4th year follow-up**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

**REQUEST FOR LABORATORY TESTS**  
**4th year follow-up**

<input type="checkbox"/>	BACILLOSCOPY (Register result in Block V, page 119)
<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 122)

OBS:

---



---



---

\_\_\_\_\_  
Signature and stamp of medical examiner




PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

## SIMPLIFIED EVALUATION OF NEURAL FUNCTIONS AND COMPLICATIONS 4th year follow-up





<b>Face</b>		
<b>Nose</b>	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>	<b>R</b>	<b>L</b>
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>	<b>R</b>	<b>L</b>
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
<p>key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours</p> <p><b>Mobile claw: M;</b> <b>rigid claw: R;</b> bone absorption:  wound: </p>	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			
PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular	<b>R</b>	<b>L</b>
Posterior tibial		



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

#### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

Signature and stamp of medical examiner

## CLINICAL DERMATOLOGICAL EVALUATION - 5th year follow-up

CLINICAL DERMATOLOGICAL EVALUATION - 5th year follow-up					
Skin Lesions		1 Remission	2 Improvement	3 Unchanged	4 Worsening
	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				
Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				
<input type="checkbox"/> Any signs/symptoms of leprosy reaction?	1 – Yes    In this case, fill out the form for reactions in block V, <b>for each new episode*</b> 2 – No 3—Continued symptoms of previous reaction				
<input type="checkbox"/> Any signs/symptoms of relapse?	1 – Yes    In this case, fill out the relapse form in block V, <b>page 137*</b> 2 – No				

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**  
**5th year follow-up**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

**REQUEST FOR LABORATORY TESTS**  
**5th year follow-up**

<input type="checkbox"/>	BACILLOSCOPY (Register results in Block V, page 119)
<input type="checkbox"/>	C-REACTIVE PROTEIN (Register results in Block V, page 122)

OBS:

---



---



---

\_\_\_\_\_  
Signature and stamp of medical examiner




PATIENT INITIALS						PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS**  
**5th year follow-up**





<b>Face</b>		
<b>Nose</b>		
	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>		
	<b>R</b>	<b>L</b>
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>		
	<b>R</b>	<b>L</b>
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger			
Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb			
Abduction of the thumb (median nerve)			
Elevates wrist			
Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed

<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours	
Mobile claw: M; rigid claw: R; bone absorption:  wound: 	



\_\_\_\_\_  
Signature and stamp of medical examiner





PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			
PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			

Lower limbs			
Main complaint			
Nerve Palpation		R	L
Fibular			
Posterior tibial			



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels ✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation / /								

#### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

Signature and stamp of medical examiner

## CLINICAL DERMATOLOGICAL EVALUATION - 6th year follow-up

		1 Remission	2 Improvement	3 Unchanged	4 Worsening
Skin Lesions	1. Colour				
	2. Sensibility				
	3. Infiltration				
	4. Other				
Symptoms and signs of side effects from MDT	Sign/symptom	Absent	mild	moderate	severe
	1. Itching				
	2. Dry skin				
	3. Skin pigmentation				
	4. Rash				
	5. Erythrodermia				
	6. Photosensitivity				
	7. Abdominal pain				
	8. Constipation				
	9. Nausea				
	10. Vomiting				
	11. Diarrhoea				
	12. Anorexia				
	13. Jaundice				
	14. Pallor				
	15. Cyanosis				
	16. Bleeding				
	17. Weight loss				
	18. Dyspnoea				
	19. Asthenia				
	20. Fever				
	21. Myalgia				
	22. Headache				
	23. Depression				
<input type="checkbox"/> Any signs/symptoms of leprosy reaction?	1 – Yes In this case, fill out the form for reactions in block V, <b>for each new episode*</b> 2 – No 3—Continued symptoms of previous reaction				
<input type="checkbox"/> Any signs/symptoms of relapse?	1 – Yes In this case, fill out the relapse form in block V, <b>page 137*</b> 2 – No				

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**  
6th year follow-up

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

**REQUEST FOR LABORATORY TESTS**  
6th year follow-up

<input type="checkbox"/>	BACILLOSCOPY (Register results in Block V, page 119)
<input type="checkbox"/>	C-REACTIVE PROTEIN (Register results in Block V, page 122)

OBS:

---



---



---

\_\_\_\_\_  
Signature and stamp of medical examiner







PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS  
6th year follow-up**





<b>Face</b>			
<b>Nose</b>		<b>R</b>	<b>L</b>
Main complaint			
dryness (S/N)			
abrasions (S/N)			
Perforation of the septum (S/N)			
<b>Eyes</b>		<b>R</b>	<b>L</b>
Main complaint			
Closes eyes w/o force (mm)			
Closes eyes w/ force (mm)			
Cornea diminished sensibility (S/N)			
Cornea opacity (S/N)			
Cataract (S/N)			
Visual acuity			

<b>Upper limbs</b>			
Main complaint			
<b>Nerve palpation</b>		<b>R</b>	<b>L</b>
Ulnar			
Median			
Radius			

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger			
Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb			
Abduction of the thumb (median nerve)			
Elevates wrist			
Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours	
Mobile claw: M; rigid claw: R; bone absorption:  wound: 	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

Lower limbs			
Main complaint			
Nerve Palpation		R	L
Fibular			
Posterior tibial			



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels ✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation / /								

#### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

Signature and stamp of medical examiner

# BLOCK V

## Miscellaneous forms

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**DIAGNOSIS AND FOLLOW-UP OF REACTION FORM**

EPISODE NUMBER:  REACTION

1	Adverse reaction	18	Neuritis
2	ENL	19	Neuritis + Adverse reaction
3	Necrotizing ENL	20	Neuritis + ENL
4	Polymorphous erythema	21	Neuritis + Mixed reaction
5	Arthritis	22	Neuritis + Necrotizing ENL
6	Lymphadenopathy	23	Neuritis + Polymorphous erythema
7	Orchitis	24	Neuritis + Arthritis
8	Iritis/Iridocyclitis	25	Neuritis + Lymphadenopathy
9	Reaction hand and foot	26	Neuritis + Orchitis
10	ENL+ Necrotizing ENL	27	Neuritis + Iritis/ Iridocyclitis
11	ENL+ polymorphous erythema	28	Neuritis + Reaction hand/foot
12	ENL+ orchitis	29	Neuritis + ENL+ Necrotizing ENL
13	ENL+ arthritis	30	Neuritis + ENL+ Polymorphous erythema
14	ENL+ Lymphadenopathy	31	Neuritis + ENL+ orchitis
15	ENL+ Iritis/ Iridocyclitis	32	Neuritis + ENL+ arthritis
16	ENL+ Reaction hand/foot	33	Neuritis + ENL+ Lymphadenopathy
17	Mixed reaction/ Type 1 + Type 2	34	Neuritis + ENL+ Iritis/Iridocyclitis
		35	Neuritis + ENL+ Reaction hand/foot

**Involvement:**

1	Cutaneous	4	Cutaneous + Systemic
2	Neural	5	Neural + Systemic
3	Cutaneous + Neural	6	Cutaneous + Neural + Systemic

**Possible triggering factors:**

1	Concomitant infections	5	Medication
2	Pregnancy	6	Vaccination
3	Surgery	7	Not identified
4	Emotional distress	8	Others

**Treatment:**

1	Corticosteroids	8	Thalidomide+ Clofazimine
2	Thalidomide	9	Thalidomide + Pentoxifylline
3	Clofazimine	10	Corticosteroids + Thalidomide + Clofazimine
4	Pentoxifylline	11	Corticosteroids + Pentoxifylline + Thalidomide
5	Corticosteroids + Thalidomide	12	Corticosteroids + Pentoxifylline + Clofazimine
6	Corticosteroids + Clofazimine	13	Corticosteroids + Pentoxifylline + Clofazimine + Thalidomide
7	Corticosteroids + Pentoxifylline	14	Others

---

Signature and stamp of investigator

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**  
**Diagnosis and follow-up of reaction episodes**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**REQUEST FOR LABORATORY TESTS – reaction episodes**

	C-REACTIVE PROTEIN (Register result in the Block V, page 123)
--	---

OBS:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner






PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS**  
**Diagnosis and follow-up of reactions**



<b>Face</b>		
<b>Nose</b>		
	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>		
	<b>R</b>	<b>L</b>
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>		
	<b>R</b>	<b>L</b>
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours <b>Mobile claw: M; rigid claw: R; bone absorption: ☒ wound: ☉</b>	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			
PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			

<b>Lower limbs</b>		
Main complaint		
<b>Nerve Palpation</b>		
Fibular	<b>R</b>	<b>L</b>
Posterior tibial		



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

### Classification of disability grade

Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**DIAGNOSIS AND FOLLOW-UP OF REACTION FORM**

EPISODE NUMBER: \_\_\_\_ REACTION

1	Adverse reaction	18	Neuritis
2	ENL	19	Neuritis + Adverse reaction
3	Necrotizing ENL	20	Neuritis + ENL
4	Polymorphous erythema	21	Neuritis + Mixed reaction
5	Arthritis	22	Neuritis + Necrotizing ENL
6	Lymphadenopathy	23	Neuritis + Polymorphous erythema
7	Orchitis	24	Neuritis + Arthritis
8	Iritis/Iridocyclitis	25	Neuritis + Lymphadenopathy
9	Reaction hand and foot	26	Neuritis + Orchitis
10	ENL+ Necrotizing ENL	27	Neuritis + Iritis/ Iridocyclitis
11	ENL+ polymorphous erythema	28	Neuritis + Reaction hand/foot
12	ENL+ orchitis	29	Neuritis + ENL+ Necrotizing ENL
13	ENL+ arthritis	30	Neuritis + ENL+ Polymorphous erythema
14	ENL+ Lymphadenopathy	31	Neuritis + ENL+ orchitis
15	ENL+ Iritis/ Iridocyclitis	32	Neuritis + ENL+ arthritis
16	ENL+ Reaction hand/foot	33	Neuritis + ENL+ Lymphadenopathy
17	Mixed reaction/ Type 1 + Type 2	34	Neuritis + ENL+ Iritis/Iridocyclitis
		35	Neuritis + ENL+ Reaction hand/foot

**Involvement:**

1	Cutaneous	4	Cutaneous + Systemic
2	Neural	5	Neural + Systemic
3	Cutaneous + Neural	6	Cutaneous + Neural + Systemic

**Possible triggering factors:**

1	Concomitant infections	5	Medication
2	Pregnancy	6	Vaccination
3	Surgery	7	Not identified
4	Emotional distress	8	Others

**Treatment:**

1	Corticosteroids	8	Thalidomide+ Clofazimine
2	Thalidomide	9	Thalidomide + Pentoxifylline
3	Clofazimine	10	Corticosteroids + Thalidomide + Clofazimine
4	Pentoxifylline	11	Corticosteroids + Pentoxifylline + Thalidomide
5	Corticosteroids + Thalidomide	12	Corticosteroids + Pentoxifylline + Clofazimine
6	Corticosteroids + Clofazimine	13	Corticosteroids + Pentoxifylline + Clofazimine + Thalidomide
7	Corticosteroids + Pentoxifylline	14	Others

---

Signature and stamp of investigator

PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**  
**Diagnosis and follow-up of reaction episodes**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**REQUEST FOR LABORATORY TESTS – reaction episodes**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 123)
--------------------------	---

OBS:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner




PATIENT INITIALS						PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS**  
**Diagnosis and follow-up of reaction episodes**





<b>Face</b>		
<b>Nose</b>		
	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>		
	<b>R</b>	<b>L</b>
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>		
	<b>R</b>	<b>L</b>
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours <b>Mobile claw: M</b> ; <b>rigid claw: R</b> ; bone absorption:  wound: 	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			
PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular		<b>R</b> <b>L</b>
Posterior tibial		



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation			<b>R</b>	<b>L</b>
Elevates hallux Hallux extension (fibular nerve)				
Elevate foot Foot dorsiflexion (fibular nerve)				

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
<b>R</b>	<b>L</b>
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**DIAGNOSIS AND FOLLOW-UP OF REACTION FORM**  
**REACTION**

EPISODE NUMBER: \_\_\_\_

1	Adverse reaction	18	Neuritis
2	ENL	19	Neuritis + Adverse reaction
3	Necrotizing ENL	20	Neuritis + ENL
4	Polymorphous erythema	21	Neuritis + Mixed reaction
5	Arthritis	22	Neuritis + Necrotizing ENL
6	Lymphadenopathy	23	Neuritis + Polymorphous erythema
7	Orchitis	24	Neuritis + Arthritis
8	Iritis/Iridocyclitis	25	Neuritis + Lymphadenopathy
9	Reaction hand and foot	26	Neuritis + Orchitis
10	ENL+ Necrotizing ENL	27	Neuritis + Iritis/ Iridocyclitis
11	ENL+ polymorphous erythema	28	Neuritis + Reaction hand/foot
12	ENL+ orchitis	29	Neuritis + ENL+ Necrotizing ENL
13	ENL+ arthritis	30	Neuritis + ENL+ Polymorphous erythema
14	ENL+ Lymphadenopathy	31	Neuritis + ENL+ orchitis
15	ENL+ Iritis/ Iridocyclitis	32	Neuritis + ENL+ arthritis
16	ENL+ Reaction hand/foot	33	Neuritis + ENL+ Lymphadenopathy
17	Mixed reaction/ Type 1 + Type 2	34	Neuritis + ENL+ Iritis/Iridocyclitis
		35	Neuritis + ENL+ Reaction hand/foot

**Involvement:**

1	Cutaneous	4	Cutaneous + Systemic
2	Neural	5	Neural + Systemic
3	Cutaneous + Neural	6	Cutaneous + Neural + Systemic

**Possible triggering factors:**

1	Concomitant infections	5	Medication
2	Pregnancy	6	Vaccination
3	Surgery	7	Not identified
4	Emotional distress	8	Others

**Treatment:**

1	Corticosteroids	8	Thalidomide+ Clofazimine
2	Thalidomide	9	Thalidomide + Pentoxifylline
3	Clofazimine	10	Corticosteroids + Thalidomide + Clofazimine
4	Pentoxifylline	11	Corticosteroids + Pentoxifylline + Thalidomide
5	Corticosteroids + Thalidomide	12	Corticosteroids + Pentoxifylline + Clofazimine
6	Corticosteroids + Clofazimine	13	Corticosteroids + Pentoxifylline + Clofazimine + Thalidomide
7	Corticosteroids + Pentoxifylline	14	Others

---

Signature and stamp of investigator

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

## EXAMINATION OF PERIPHERAL NERVES

### Diagnosis and follow-up of reaction episodes

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

## REQUEST OF LABORATORY TESTS – Reaction episodes

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 123)
--------------------------	---

OBS:

---



---



---

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--




## SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS

### Diagnosis and follow-up of reaction episodes



Face		
Nose	R	L
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
Eyes	R	L
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

Upper limbs		
Nerve palpation	R	L
Main complaint		
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	
key: lilac pen / monofilament (2g): feels ✓; does not feel X; or monofilaments: follow colours <b>Mobile claw: M; rigid claw: R; bone absorption: ☒</b> wound: ☉	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			
PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular		<b>R</b>
Posterior tibial		<b>L</b>



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation			<b>R</b>	<b>L</b>
Elevates hallux Hallux extension (fibular nerve)				
Elevate foot Foot dorsiflexion (fibular nerve)				

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
<b>R</b>	<b>L</b>
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**DIAGNOSIS AND FOLLOW-UP OF REACTION FORM**  
**REACTION**

EPISODE NUMBER: \_\_\_\_

1	Adverse reaction	18	Neuritis
2	ENL	19	Neuritis + Adverse reaction
3	Necrotizing ENL	20	Neuritis + ENL
4	Polymorphous erythema	21	Neuritis + Mixed reaction
5	Arthritis	22	Neuritis + Necrotizing ENL
6	Lymphadenopathy	23	Neuritis + Polymorphous erythema
7	Orchitis	24	Neuritis + Arthritis
8	Iritis/Iridocyclitis	25	Neuritis + Lymphadenopathy
9	Reaction hand and foot	26	Neuritis + Orchitis
10	ENL+ Necrotizing ENL	27	Neuritis + Iritis/ Iridocyclitis
11	ENL+ polymorphous erythema	28	Neuritis + Reaction hand/foot
12	ENL+ orchitis	29	Neuritis + ENL+ Necrotizing ENL
13	ENL+ arthritis	30	Neuritis + ENL+ Polymorphous erythema
14	ENL+ Lymphadenopathy	31	Neuritis + ENL+ orchitis
15	ENL+ Iritis/ Iridocyclitis	32	Neuritis + ENL+ arthritis
16	ENL+ Reaction hand/foot	33	Neuritis + ENL+ Lymphadenopathy
17	Mixed reaction/ Type 1 + Type 2	34	Neuritis + ENL+ Iritis/Iridocyclitis
		35	Neuritis + ENL+ Reaction hand/foot

**Involvement:**

1	Cutaneous	4	Cutaneous + Systemic
2	Neural	5	Neural + Systemic
3	Cutaneous + Neural	6	Cutaneous + Neural + Systemic

**Possible triggering factors:**

1	Concomitant infections	5	Medication
2	Pregnancy	6	Vaccination
3	Surgery	7	Not identified
4	Emotional distress	8	Others

**Treatment:**

1	Corticosteroids	8	Thalidomide+ Clofazimine
2	Thalidomide	9	Thalidomide + Pentoxifylline
3	Clofazimine	10	Corticosteroids + Thalidomide + Clofazimine
4	Pentoxifylline	11	Corticosteroids + Pentoxifylline + Thalidomide
5	Corticosteroids + Thalidomide	12	Corticosteroids + Pentoxifylline + Clofazimine
6	Corticosteroids + Clofazimine	13	Corticosteroids + Pentoxifylline + Clofazimine + Thalidomide
7	Corticosteroids + Pentoxifylline	14	Others

---

Signature and stamp of investigator

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**EXAMINATION OF PERIPHERAL NERVES**  
**Diagnosis and follow-up of reaction episodes**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 – Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**REQUEST OF LABORATORY TESTS – reaction episodes**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 123)
--------------------------	---

OBS:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner







PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS**  
**Diagnosis and follow-up of reaction episodes**





<b>Face</b>		
Nose	R	L
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>		
R	L	
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>		
R	L	
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		R	L
Opens little finger			
Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb			
Abduction of the thumb (median nerve)			
Elevates wrist			
Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
R	L
	
key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours <b>Mobile claw: M;</b> <b>rigid claw: R;</b> bone absorption:  wound: 	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			
PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular		<b>R</b>
Posterior tibial		<b>L</b>



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation			
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

#### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

### REACTION DIAGNOSIS AND FOLLOW-UP FORM REACTION

EPISODE NUMBER: \_\_\_\_

1	Adverse reaction	18	Neuritis
2	ENL	19	Neuritis + Adverse reaction
3	Necrotizing ENL	20	Neuritis + ENL
4	Polymorphous erythema	21	Neuritis + Mixed reaction
5	Arthritis	22	Neuritis + Necrotizing ENL
6	Lymphadenopathy	23	Neuritis + Polymorphous erythema
7	Orchitis	24	Neuritis + Arthritis
8	Iritis/Iridocyclitis	25	Neuritis + Lymphadenopathy
9	Reaction hand and foot	26	Neuritis + Orchitis
10	ENL+ Necrotizing ENL	27	Neuritis + Iritis/ Iridocyclitis
11	ENL+ polymorphous erythema	28	Neuritis + Reaction hand/foot
12	ENL+ orchitis	29	Neuritis + ENL+ Necrotizing ENL
13	ENL+ arthritis	30	Neuritis + ENL+ Polymorphous erythema
14	ENL+ Lymphadenopathy	31	Neuritis + ENL+ orchitis
15	ENL+ Iritis/ Iridocyclitis	32	Neuritis + ENL+ arthritis
16	ENL+ Reaction hand/foot	33	Neuritis + ENL+ Lymphadenopathy
17	Mixed reaction/ Type 1 + Type 2	34	Neuritis + ENL+ Iritis/Iridocyclitis
		35	Neuritis + ENL+ Reaction hand/foot

**Involvement:**

1	Cutaneous	4	Cutaneous + Systemic
2	Neural	5	Neural + Systemic
3	Cutaneous + Neural	6	Cutaneous + Neural + Systemic

**Possible triggering factors:**

1	Concomitant infections	5	Medication
2	Pregnancy	6	Vaccination
3	Surgery	7	Not identified
4	Emotional distress	8	Others

**Treatment:**

1	Corticosteroids	8	Thalidomide+ Clofazimine
2	Thalidomide	9	Thalidomide + Pentoxifylline
3	Clofazimine	10	Corticosteroids + Thalidomide + Clofazimine
4	Pentoxifylline	11	Corticosteroids + Pentoxifylline + Thalidomide
5	Corticosteroids + Thalidomide	12	Corticosteroids + Pentoxifylline + Clofazimine
6	Corticosteroids + Clofazimine	13	Corticosteroids + Pentoxifylline + Clofazimine + Thalidomide
7	Corticosteroids + Pentoxifylline	14	Others

---

Signature and stamp of investigator

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**EXAMINATION OF PERIPHERAL NERVES**  
**Diagnosis and follow-up of reaction episodes**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
 Signature and stamp of medical examiner

**REQUEST OF LABORATORY EXAMS – reaction episodes**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 123)
--------------------------	---

OBS:  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

\_\_\_\_\_  
 Signature and stamp from medical examiner



PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--




## SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS

### Diagnosis and follow-up of reaction episodes





Face		
Nose	R	L
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
Eyes	R	L
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

Upper limbs		
Nerve palpation	R	L
Main complaint		
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	
<p>key: lilac pen / monofilament (2g): feels ✓; does not feel X; or monofilaments: follow colours  <b>Mobile claw: M</b>; <b>rigid claw: R</b>; bone absorption:  wound: </p>	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular		<b>R</b>
Posterior tibial		<b>L</b>



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation			<b>R</b>	<b>L</b>
Elevates hallux				
Hallux extension (fibular nerve)				
Elevate foot				
Foot dorsiflexion (fibular nerve)				

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
<b>R</b>	<b>L</b>
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**DIAGNOSIS AND FOLLOW-UP OF REACTION FORM  
REACTION**

EPISODE NUMBER: \_\_\_\_

1	Adverse reaction	18	Neuritis
2	ENL	19	Neuritis + Adverse reaction
3	Necrotizing ENL	20	Neuritis + ENL
4	Polymorphous erythema	21	Neuritis + Mixed reaction
5	Arthritis	22	Neuritis + Necrotizing ENL
6	Lymphadenopathy	23	Neuritis + Polymorphous erythema
7	Orchitis	24	Neuritis + Arthritis
8	Iritis/Iridocyclitis	25	Neuritis + Lymphadenopathy
9	Reaction hand and foot	26	Neuritis + Orchitis
10	ENL+ Necrotizing ENL	27	Neuritis + Iritis/ Iridocyclitis
11	ENL+ polymorphous erythema	28	Neuritis + Reaction hand/foot
12	ENL+ orchitis	29	Neuritis + ENL+ Necrotizing ENL
13	ENL+ arthritis	30	Neuritis + ENL+ Polymorphous erythema
14	ENL+ Lymphadenopathy	31	Neuritis + ENL+ orchitis
15	ENL+ Iritis/ Iridocyclitis	32	Neuritis + ENL+ arthritis
16	ENL+ Reaction hand/foot	33	Neuritis + ENL+ Lymphadenopathy
17	Mixed reaction/ Type 1 + Type 2	34	Neuritis + ENL+ Iritis/Iridocyclitis
		35	Neuritis + ENL+ Reaction hand/foot

**Involvement:**

1	Cutaneous	4	Cutaneous + Systemic
2	Neural	5	Neural + Systemic
3	Cutaneous + Neural	6	Cutaneous + Neural + Systemic

**Possible triggering factors:**

1	Concomitant infections	5	Medication
2	Pregnancy	6	Vaccination
3	Surgery	7	Not identified
4	Emotional distress	8	Others

**Treatment:**

1	Corticosteroids	8	Thalidomide+ Clofazimine
2	Thalidomide	9	Thalidomide + Pentoxifylline
3	Clofazimine	10	Corticosteroids + Thalidomide + Clofazimine
4	Pentoxifylline	11	Corticosteroids + Pentoxifylline + Thalidomide
5	Corticosteroids + Thalidomide	12	Corticosteroids + Pentoxifylline + Clofazimine
6	Corticosteroids + Clofazimine	13	Corticosteroids + Pentoxifylline + Clofazimine + Thalidomide
7	Corticosteroids + Pentoxifylline	14	Others

---

Signature and stamp of investigator

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**EXAMINATION OF PERIPHERAL NERVES**  
**Diagnosis and follow-up of reaction episodes**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**REQUEST OF LABORATORY EXAMS – reaction episodes**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 123)
--------------------------	---

OBS:

---



---



---



---

\_\_\_\_\_  
Signature and stamp of medical examiner




PATIENT INITIALS						PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS**  
**Diagnosis and follow-up of reaction episodes**





<b>Face</b>		
<b>Nose</b>		
	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>		
	<b>R</b>	<b>L</b>
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>		
	<b>R</b>	<b>L</b>
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed

<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
<p>key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours  <b>Mobile claw: M</b>; <b>rigid claw: R</b>; bone absorption:  wound: </p>	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**REACTION DIAGNOSIS AND FOLLOW-UP FORM**

EPISODE NUMBER: \_\_\_\_

**REACTION**

1	Adverse reaction	18	Neuritis
2	ENL	19	Neuritis + Adverse reaction
3	Necrotizing ENL	20	Neuritis + ENL
4	Polymorphous erythema	21	Neuritis + Mixed reaction
5	Arthritis	22	Neuritis + Necrotizing ENL
6	Lymphadenopathy	23	Neuritis + Polymorphous erythema
7	Orchitis	24	Neuritis + Arthritis
8	Iritis/Iridocyclitis	25	Neuritis + Lymphadenopathy
9	Reaction hand and foot	26	Neuritis + Orchitis
10	ENL+ Necrotizing ENL	27	Neuritis + Iritis/ Iridocyclitis
11	ENL+ polymorphous erythema	28	Neuritis + Reaction hand/foot
12	ENL+ orchitis	29	Neuritis + ENL+ Necrotizing ENL
13	ENL+ arthritis	30	Neuritis + ENL+ Polymorphous erythema
14	ENL+ Lymphadenopathy	31	Neuritis + ENL+ orchitis
15	ENL+ Iritis/ Iridocyclitis	32	Neuritis + ENL+ arthritis
16	ENL+ Reaction hand/foot	33	Neuritis + ENL+ Lymphadenopathy
17	Mixed reaction/ Type 1 + Type 2	34	Neuritis + ENL+ Iritis/Iridocyclitis
		35	Neuritis + ENL+ Reaction hand/foot

**Involvement:**

1	Cutaneous	4	Cutaneous + Systemic
2	Neural	5	Neural + Systemic
3	Cutaneous + Neural	6	Cutaneous + Neural + Systemic

**Possible triggering factors:**

1	Concomitant infections	5	Medication
2	Pregnancy	6	Vaccination
3	Surgery	7	Not identified
4	Emotional distress	8	Others

**Treatment:**

1	Corticosteroids	8	Thalidomide+ Clofazimine
2	Thalidomide	9	Thalidomide + Pentoxifylline
3	Clofazimine	10	Corticosteroids + Thalidomide + Clofazimine
4	Pentoxifylline	11	Corticosteroids + Pentoxifylline + Thalidomide
5	Corticosteroids + Thalidomide	12	Corticosteroids + Pentoxifylline + Clofazimine
6	Corticosteroids + Clofazimine	13	Corticosteroids + Pentoxifylline + Clofazimine + Thalidomide
7	Corticosteroids + Pentoxifylline	14	Others

---

Signature and stamp of investigator

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**EXAMINATION OF PERIPHERAL NERVES**  
**Diagnosis and follow-up of reaction episodes**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**REQUEST FOR LABORATORY EXAMS – reaction episodes**

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 123)
--------------------------	---

OBS:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner









PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS**  
**Diagnosis and follow-up of reaction episodes**





<b>Face</b>		
Nose	R	L
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>		
R	L	
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>		
R	L	
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		R	L
Opens little finger			
Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb			
Abduction of the thumb (median nerve)			
Elevates wrist			
Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
R	L
	
key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours <b>Mobile claw: M;</b> <b>rigid claw: R;</b> bone absorption:  wound: 	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

Lower limbs			
Main complaint			
Nerve Palpation		R	L
Fibular			
Posterior tibial			



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**DIAGNOSIS AND FOLLOW-UP OF REACTION FORM**  
**REACTION**

EPISODE NUMBER: \_\_\_\_

1	Adverse reaction	18	Neuritis
2	ENL	19	Neuritis + Adverse reaction
3	Necrotizing ENL	20	Neuritis + ENL
4	Polymorphous erythema	21	Neuritis + Mixed reaction
5	Arthritis	22	Neuritis + Necrotizing ENL
6	Lymphadenopathy	23	Neuritis + Polymorphous erythema
7	Orchitis	24	Neuritis + Arthritis
8	Iritis/Iridocyclitis	25	Neuritis + Lymphadenopathy
9	Reaction hand and foot	26	Neuritis + Orchitis
10	ENL+ Necrotizing ENL	27	Neuritis + Iritis/ Iridocyclitis
11	ENL+ polymorphous erythema	28	Neuritis + Reaction hand/foot
12	ENL+ orchitis	29	Neuritis + ENL+ Necrotizing ENL
13	ENL+ arthritis	30	Neuritis + ENL+ Polymorphous erythema
14	ENL+ Lymphadenopathy	31	Neuritis + ENL+ orchitis
15	ENL+ Iritis/ Iridocyclitis	32	Neuritis + ENL+ arthritis
16	ENL+ Reaction hand/foot	33	Neuritis + ENL+ Lymphadenopathy
17	Mixed reaction/ Type 1 + Type 2	34	Neuritis + ENL+ Iritis/Iridocyclitis
		35	Neuritis + ENL+ Reaction hand/foot

**Involvement:**

1	Cutaneous	4	Cutaneous + Systemic
2	Neural	5	Neural + Systemic
3	Cutaneous + Neural	6	Cutaneous + Neural + Systemic

**Possible triggering factors:**

1	Concomitant infections	5	Medication
2	Pregnancy	6	Vaccination
3	Surgery	7	Not identified
4	Emotional distress	8	Others

**Treatment:**

1	Corticosteroids	8	Thalidomide+ Clofazimine
2	Thalidomide	9	Thalidomide + Pentoxifylline
3	Clofazimine	10	Corticosteroids + Thalidomide + Clofazimine
4	Pentoxifylline	11	Corticosteroids + Pentoxifylline + Thalidomide
5	Corticosteroids + Thalidomide	12	Corticosteroids + Pentoxifylline + Clofazimine
6	Corticosteroids + Clofazimine	13	Corticosteroids + Pentoxifylline + Clofazimine + Thalidomide
7	Corticosteroids + Pentoxifylline	14	Others

---

Signature and stamp of investigator

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

## EXAMINATION OF PERIPHERAL NERVES

### Diagnosis and follow-up of reaction episodes

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

## REQUEST FOR LABORATORY TESTS – reactions

<input type="checkbox"/>	C-REACTIVE PROTEIN (Register result in Block V, page 123)
--------------------------	---

OBS:

---



---



---



---

\_\_\_\_\_  
Signature and stamp of medical examiner




PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS**  
**Diagnosis and follow-up of reaction episodes**





<b>Face</b>		
<b>Nose</b>		
	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>		
	<b>R</b>	<b>L</b>
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>		
	<b>R</b>	<b>L</b>
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb Abduction of the thumb (median nerve)			
Elevates wrist Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
<p>key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours  <b>Mobile claw: M</b>; <b>rigid claw: R</b>; bone absorption:  wound: </p>	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						PATIENT NUMBER:						DATE OF VISIT:			
------------------	--	--	--	--	--	-----------------	--	--	--	--	--	----------------	--	--	--

Lower limbs			
Main complaint			
Nerve Palpation		R	L
Fibular			
Posterior tibial			



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation		R	L
Elevates hallux Hallux extension (fibular nerve)			
Elevate foot Foot dorsiflexion (fibular nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
R	L
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

PATIENT INITIALS:					PATIENT NUMBER:				
-------------------	--	--	--	--	-----------------	--	--	--	--

### BACILLOSCOPY RESULTS

	Right ear lobe	Left ear lobe	Elbow R	Elbow L	Average of bacteriological indexes – BI
Beginning of the study Date __/__/__					
End of treatment* Date __/__/__					
1st year visit post-discharge Date __/__/__					
2 <sup>nd</sup> year visit post-discharge Date __/__/__					
3rd year visit post-discharge Date __/__/__					
4th year visit post-discharge Date __/__/__					
5th year visit post-discharge Date __/__/__					
6th year visit post-discharge Date __/__/__					

\* 13th month for groups 3 and 4 of multibacillary patients

---

Signature and stamp of medical examiner

PATIENT INITIALS:					PATIENT NUMBER:				
-------------------	--	--	--	--	-----------------	--	--	--	--

### SULFONURIA RESULTS

SULFONURIA – RESULTS ( Positive or negative)		
Test	Result	Comments
1st month date ___ / ___ / ___		
2nd month date ___ / ___ / ___		
3rd month date ___ / ___ / ___		
4th month date ___ / ___ / ___		
5th month date ___ / ___ / ___		
6th month date ___ / ___ / ___		
7th month * date ___ / ___ / ___		
8th month * date ___ / ___ / ___		
9th month * date ___ / ___ / ___		
10th month * date ___ / ___ / ___		
11th month * date ___ / ___ / ___		
12th month * date ___ / ___ / ___		

\* For group 4 of multibacillary patients

---

Signature and stamp of medical examiner



PATIENT INITIALS:					PATIENT NUMBER:				
-------------------	--	--	--	--	-----------------	--	--	--	--

### C- REACTIVE PROTEIN RESULTS – Monthly

TEST	Results	Clinically significant ("√")	COMMENTS If test was not done, indicate with ND
BEGINNING OF THE STUDY 1st dose/ Date			
2nd DOSE/ Date			
3rd DOSE / Date			
4th DOSE / Date			
5th DOSE / Date			
6th DOSE / Date			
7th DOSE / Date			
8th DOSE / Date			
9th DOSE / Date			
10th DOSE / Date			
11th DOSE / Date			
12th DOSE / Date			
End of treatment / Date			

**Normal value < 8 units mg/L**

**\* For groups 3 and 4 of Multibacillary patients**

\_\_\_\_\_  
Signature and stamp of medical examiner

PATIENT INITIALS:					PATIENT NUMBER:				
-------------------	--	--	--	--	-----------------	--	--	--	--

### C - REACTIVE PROTEIN RESULTS – Annual

TEST	Results	Clinically significant ("✓")	COMMENTS If test was not done, indicate with ND
1st Year/ Date			
2nd Year/ Date			
3rd Year/ Date			
4th Year/ Date			
5th Year/ Date			
6th Year/ Date			

Normal value < 8 units mg/L

---

Signature and stamp of medical examiner



PATIENT INITIALS:					PATIENT NUMBER:				
-------------------	--	--	--	--	-----------------	--	--	--	--

### REGISTRATION OF DOSE UNDER STUDY

VISIT	Date of Visit (day /month/ year)	Number of pills given	Lot no.	Expiration -- / -- --
BEGINNING OF THE STUDY 1st DOSE	__ / __ / __			
2nd DOSE	__ / __ / __			
3rd DOSE	__ / __ / __			
4th DOSE	__ / __ / __			
5th DOSE	__ / __ / __			
6th DOSE	__ / __ / __			
7th DOSE*	__ / __ / __			
8th DOSE*	__ / __ / __			
9th DOSE*	__ / __ / __			
10th DOSE*	__ / __ / __			
11th DOSE*	__ / __ / __			
12th DOSE*	__ / __ / __			

**\* For group 4 of multibacillary patients**

"I affirm that the information on this form was verified by me and is true."

\_\_\_\_\_  
Signature and stamp of medical examiner

DATE \_\_ / \_\_ / \_\_







PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

### CLINICAL DERMATOLOGICAL EVALUATION – RELAPSE

KEY: 1. Altered    2. Normal	Alterations observed
<input type="checkbox"/> Cardiovascular	
<input type="checkbox"/> Musculoskeletal	
<input type="checkbox"/> Respiratory	
<input type="checkbox"/> Gastrointestinal	
<input type="checkbox"/> Liver	
<input type="checkbox"/> Metabolic/Endocrine	
<input type="checkbox"/> Genital-Urinary	
<input type="checkbox"/> Neurological	
<input type="checkbox"/> Psychiatric	
<input type="checkbox"/> Haematological/ Lymphatic	
<input type="checkbox"/> Musculoskeletal	
<input type="checkbox"/> Signs/ symptoms of reaction present?	1 – Yes 2 – No
<input type="checkbox"/> Other (specify)	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			

**EXAMINATION OF PERIPHERAL NERVES - RELAPSE FORM**

NERVES	KEY NERVE EXAMINATION 0 - Normal 1- Thickened 2- Nerve abscess		KEY SCALE OF INDICATED NEURAL PAIN 0 - No pain 1 - Weak pain 2 - Strong pain	
	RIGHT	LEFT	RIGHT	LEFT
Ulnar				
Median				
Radial				
Fibular				
Posterior Tibial				
Others				

\_\_\_\_\_  
Signature and stamp of medical examiner

**REQUEST FOR LABORATORY EXAMS - RELAPSE FORM**

<input type="checkbox"/>	BACILLOSCOPY
<input type="checkbox"/>	HISTOPATHOLOGICAL
<input type="checkbox"/>	ML-FLOW <span style="float: right;">affix the tape here</span>

OBS:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_







\_\_\_\_\_  
Signature and stamp of medical examiner

**SIMPLIFIED EVALUATION OF NEURAL FUNCTION AND COMPLICATIONS  
RELAPSE FORM**





<b>Face</b>		
<b>Nose</b>		
	<b>R</b>	<b>L</b>
Main complaint		
dryness (S/N)		
abrasions (S/N)		
Perforation of the septum (S/N)		
<b>Eyes</b>		
Main complaint		
Closes eyes w/o force (mm)		
Closes eyes w/ force (mm)		
Cornea diminished sensibility (S/N)		
Cornea opacity (S/N)		
Cataract (S/N)		
Visual acuity		

<b>Upper limbs</b>		
Main complaint		
<b>Nerve palpation</b>		
	<b>R</b>	<b>L</b>
Ulnar		
Median		
Radius		

key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

<b>Strength evaluation</b>		<b>R</b>	<b>L</b>
Opens little finger			
Abduction of the 5 <sup>th</sup> finger (ulnar nerve)			
Elevates thumb			
Abduction of the thumb (median nerve)			
Elevates wrist			
Wrist extension (radial nerve)			

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contraction; 0 = paralysed



<b>SENSITIVITY EVALUATION AND STATUS INSPECTION</b>	
<b>R</b>	<b>L</b>
	
key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours	
Mobile claw: M; rigid claw: R; bone absorption:  wound: 	

\_\_\_\_\_  
Signature and stamp of medical examiner



PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			
PATIENT INITIALS						<b>PATIENT NUMBER:</b>					<b>DATE OF VISIT:</b>			

Lower limbs		
Main complaint		
Nerve Palpation		
Fibular		<b>R</b> <b>L</b>
Posterior tibial		



key: N = normal; T = thickened; P = pain; S = Tinel's sign (+)

Strength evaluation			<b>R</b>	<b>L</b>
Elevates hallux Hallux extension (fibular nerve)				
Elevate foot Foot dorsiflexion (fibular nerve)				

key: S = strong; D = diminished; P = paralysed or 5 = strong; 4 = partial resistance; 3 = complete movement; 2 = partial movement; 1 = contracture; 0 = paralysed

SENSITIVITY EVALUATION AND STATUS INSPECTION	
<b>R</b>	<b>L</b>
	

key: lilac pen / monofilament (2g): feels✓; does not feel X; or monofilaments: follow colours

Mobile claw: M; rigid claw: R; bone absorption:  wound: 

Classification of disability grade								
Evaluation date	eyes		hands		feet		Highest grade	signature
	R	L	R	L	R	L		
Evaluation ___ / ___ / ___								

#### Monofilaments

Monofilament	strength in grams	interpretation
1 – green	0.05	Normal sensitivity in hand and foot
2 – blue	0.20	Diminished sensitivity in hand and normal in foot / Difficulty in distinguishing texture (light touch)
3 – Lilac	2.00	Diminished protective sensitivity in hand / Incapable of distinguishing texture / Difficulty in distinguishing forms and temperatures
4 – dark red	4.00	Loss of protective sensitivity in hand and sometimes in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
5 - orange or red (mark with an X)	10.00	Loss of protective sensitivity in foot / loss of texture discrimination / Incapable of distinguishing forms and temperatures
6 – red circle	300.00	Only has sensation when deep pressure is applied to hand and foot
7 – black	No response to 300g monofilament	Loss of sensation even to deep pressure in hand and foot

\_\_\_\_\_  
Signature and stamp of medical examiner

## RELAPSE REGISTRATION

DERMATOLOGICAL-NEUROLOGICAL EXAM AND COMPLEMENTARY EXAMINATIONS			
Beginning of current symptoms No. of months _____	Type of lesion 7. Maculae <input type="checkbox"/> 8. Plaques <input type="checkbox"/> 9. Papules <input type="checkbox"/> 10. Diffuse infiltration 11. Nodules 12. Anaesthetic area	Colour of lesion 5. Hypo-chromatic <input type="checkbox"/> 6. Erythematose <input type="checkbox"/> 7. Hyper-chromatic <input type="checkbox"/> 8. Normal (same as surrounding skin)	Sensitivity 4. Altered 5. Inconclusive 6. Normal
Number of lesions (from 1 to 10 lesions, enter the exact number) 11. Eleven or more lesion <input type="checkbox"/> 88. linfiltração difusa <input type="checkbox"/>	Bacilloscopy 3. Negative <input type="checkbox"/> 4. Positive <input type="checkbox"/>	ML Flow 5. Negative 6. Positive 7. Inconclusive 8. Not done	Intensity of ML Flow <input type="checkbox"/> 1+ <input type="checkbox"/> 2+ <input type="checkbox"/> 3+ <input type="checkbox"/> 4+
Número de nervos comprometidos <input type="checkbox"/>	Resultado do IB ____, ____	<input type="checkbox"/>	
OPERATIONAL CLASSIFICATION			
1. Paucibacillary ( ≤ 5 skin lesions) <input type="checkbox"/> 2. Multibacillary ( ≥ 6 skin lesions) <input type="checkbox"/>			
CLINICAL CLASSIFICATION			
1. Indeterminate leprosy                      2. Tuberculoid leprosy                      3. Lepromatous leprosy 4. Borderline Tuberculoid leprosy                      5. Borderline Borderline leprosy <input type="checkbox"/> 6. Borderline Lepromatous leprosy			
BIOPSY	LEVEL OF CERTAINTY		
Slide no. _____	Date ____/____/____	[39] CONFIRMED LEPROSY [40] CONSISTENT WITH LEPROSY <input type="checkbox"/> [41] NON-SPECIFIC [42] INDICATIVE OF ANOTHER DISEASE	
BIOPSY – Beginning of study - Principle findings			
Epidermis: 1 ( ) 2 ( ) 3 ( ) 4 ( ) 5 ( )			
Dermis: Infiltrated / Inflamed: 6 ( ) 7 ( ) 8 ( ) 9 ( ) 10 ( ) 11 ( ) 12 ( ) 13 ( ) 14 ( ) 15 ( ) 16 ( )			
Nerve damage: 17 ( ) 18 ( ) 19 ( ) 20 ( )			
Vasculitis: 21 ( ) 22 ( )			
Panniculitis: 23 ( ) 24 ( ) 25 ( )			
Bacilloscopy: 26 ( ) 27 ( ) 28 ( ) 29 ( ) 30 ( ) 31 ( ) others _____			
<b>Clinical form:</b> 32- 1 [ ] 33- TT [ ] 34- BT [ ] 35- BB [ ] 36- BL [ ] 37- LL [ ] 38- [ ] Not classified			
FINAL CLASSIFICATION			
1. Indeterminate leprosy                      2. Tuberculoid leprosy                      3. Lepromatous leprosy 4. Borderline Tuberculoid leprosy                      5. Borderline Borderline leprosy <input type="checkbox"/> 6. Borderline Lepromatous leprosy			

\_\_\_\_\_  
Stamp and Signature of Researcher

PATIENT INITIALS					PATIENT NUMBER:					DATE OF VISIT:			
------------------	--	--	--	--	-----------------	--	--	--	--	----------------	--	--	--

## FORM FOR WITHDRAWAL FROM THE STUDY

	1 YES	2 NO	DATE
COMPLETED THE TREATMENT REGIMEN?			
DATE OF LAST DOSE			
WITHDRAWAL FROM THE STUDY			
REASON FOR WITHDRAWAL (More than 1 option may be chosen):	COMMENTS		
1. VIOLATION OF THE PROTOCOL, EX. BIOPSY DID NOT CONFIRM LEPROSY			
2. PATIENT WANTS TO WITHDRAW FROM THE STUDY			
3. PATIENT NOT FOUND DURING FOLLOW-UP			
4. INTERCURRENT DISEASE			
5. SIDE EFFECTS (Fill in the Form for Side Effects).			
6. CONFIRMED DIAGNOSIS OF RELAPSE (Fill out the Relapse Form)			
7. DEATH (Fill out the Death Certificate, if necessary)			
8. OTHERS (specify)			
WITHDRAWAL PROCESSED BY:			
RESEARCHER			
OTHERS			

"I affirm that the information in this form was verified by me and is true".

Date: \_\_\_/\_\_\_/\_\_\_

\_\_\_\_\_  
Signature and stamp of medical examiner