GOVT. OF WEST BENGAL
Directorate of Health Services
Leprosy Wing
Swasthya Bhawan, Wing-A, GN-29, Sector-V, Salt Lake City, Kolkata- 700 091
Telephone : 033-2333 0202/0596, Email : slskolkata@rediffmail.com

**Memo No- HLS/LEP/165-2025** 179 **Dated :** 28/02/2025

# Standard Operating Procedure of Prednisolone use in Leprosy reaction in accordance with Central Leprosy Division (CLD), Govt. of India

**To achieve the target of "Zero Leprosy by 2027", management of reactions associated with leprosy is important.**

## Definition of Reactions in leprosy:

"Reactions" in leprosy are acute episodes in the natural course of leprosy, **Reactions are not side effects of treatment but they are the body's immunological response to leprosy bacilli** and do not mean that the disease is becoming worse or that the treatment is not working. It may occur before during and after treatment. Reactions require urgent treatment as they can lead to irreversible deformities.

## Signs of reactions include:

- Existing skin lesions become reddish and swollen
- Painful reddish nodules appear.
- Peripheral nerves become painful, tender and swollen
- Signs of nerve damage such as loss of sensation and muscle weakness
- Fever and malaise
- Hands and feet may be swollen.

## Timing of Reactions

Reaction may appear before, during or after the treatment for leprosy.

## Management of reaction:

This type of patient **will have to be treated by trained MOs from Primary Health Centre level to** Tertiary **level** when they report with the significant signs and symptoms of reaction in leprosy where there is no contraindication for use of Prednisolone.

### A. Non-Pharmacological:

1. Reassurance to the patient and attendants
2. Symptomatic (ex: Hydro-therapy in case of Pyrexia etc.)

### B. Pharmacological:

Prednisolone is the drugs of choice for reaction management.

28/02/2025

**Prednisolone 10 mg (Adult)**
Dose depends on medical condition:

Adults—Dose varies from 5 to 60 milligrams (mg) per day. Medical Officer adjust the dose as needed.

| Sl. No. | Name of the Drugs | Weeks | Dosage – once daily per day | Number of Tab. |
|---|---|---|---|---|
| 1 | Prednisolone 10 mg (Wysolone) | 1st 2 weeks | 40 mg = 10 mg × 4 tabs | 56 tabs |
| 2 | | 2nd 2 weeks | 30 mg = 10 mg × 3 tabs | 42 tabs |
| 3 | | 3rd 2 weeks | 20 mg = 10 mg × 2 tabs | 28 tabs |
| 4 | | 4th 2 weeks | 10 mg = 10 mg × 1 tabs 10 mg × ½ tabs | 21 tabs |
| 5 | | 5th 2 weeks | 10 mg = 10 mg × 1 tabs | 14 tabs |
| 6 | | 6th 2 weeks | 10 mg = 10 mg × ½ tabs | 7 tabs |
| **Total Requirement of Prednisolone 10 mg per patients (Minimum requirement)** | | | | **168 tabs** |
| **But patients may require upto 168 tabs + 42 tabs with additional 2 weeks of 30 mg dosage** | | | | **210 tabs** |

- **Children (2 - 14 years)** —Dose is based on body weight and must be determined by Medical Officer. The dose is usually 0.14 to 2 mg per kilogram (kg) of body weight per day, divided and taken 3 or 4 times a day. Though Medical Officer adjust the dose as needed and the tapering regimen is as per the above table.
- The Prednisolone should be available from Primary level to Tertiary care level health facilities at OPD, indoor and emergency.
- Health units will collect Prednisolone from District Reserve Store (DRS) as it is Catalogue (CAT) item.
- MDT must not be stopped during Prednisolone therapy.

28/02/25
Director of Health Services
H&FW Department
Govt. of West Bengal

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Copy forwarded for information and necessary action to :

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28/02/2025
Dy. DHS (Lep.) & SLO
Govt. of West Bengal

# Leprosy Reaction Management Guideline in NLEP in accordance with Central Leprosy Division (CLD), Govt. of India

## Introduction

Reactions Management is a major issue in leprosy that occur due to the immunological response of the body system against *M.leprae* bacilli. These reactions may occur before, during or after the Release From Treatment (RFT) of Multi Dose Therapy (MDT), in both PB and MB cases. Severity of reaction depends on the bacterial load in the body of the affected person and strength of immunological response. Long term problems related to leprosy (deformity, disability, stigma and suffering of the patient and their family) are due to nerve damage from lepra reactions.

Sudden onset of acute inflammation of skin lesions, nerves, eyes and sometimes other organs in leprosy affected person is indicative of reactions. Lepra reaction is diagnosed by clinical examination. Early diagnosis and prompt management can prevent disability and deformity.

**Risk for developing reactions:**

Though any person affected by leprosy can develop reaction, some are more prone /predisposed/ at risk of developing reaction.

Persons with following features are more likely to develop reaction:

- Multiple lesions, Positive slit skin smear;
- Lesions close to the peripheral nerve, Lesions on the face;
- Pregnancy and Childbirth, Hormonal changes (Puberty / adolescence
- Stress (Physical, Physiological and Psychological), Inter- current infection
- Parasitic infestations

These patients should be monitored more frequently for early detection of reaction and its prompt management.

## Types of Lepra Reactions:

There are two types of Lepra Reactions:

**Type-I Lepra Reaction (Delayed Hypersensitivity) :** Also called Reversal Reaction occurs in a patient with unstable CMI, both PB and MB.

**Type-II Lepra Reaction (Immediate Hypersensitivity):** Also called Erythema Nodosum Leprosum (ENL) occurs in patients with MB leprosy with a high bacillary load.

## Type I Lepra Reaction

This may be the first presenting sign of the disease. It usually lasts for few weeks to few months but in some patients can be recurrent. It presents with inflammation of existing skin lesions. Appearance of new skin lesions are in reality sub-clinical patches, now noticed due to inflammation.

**General condition:** General condition of the patient is satisfactory. Usually there is no fever and patient does not feel ill.

**Inflammation of skin lesions:** Signs of inflammation are seen in the existing skin lesions i.e. skin lesions become red, more prominent, swollen, shiny and warm. In severe forms they may ulcerate. Lesions are usually not painful but some discomfort may be felt. Sometimes, only few patches are inflamed.

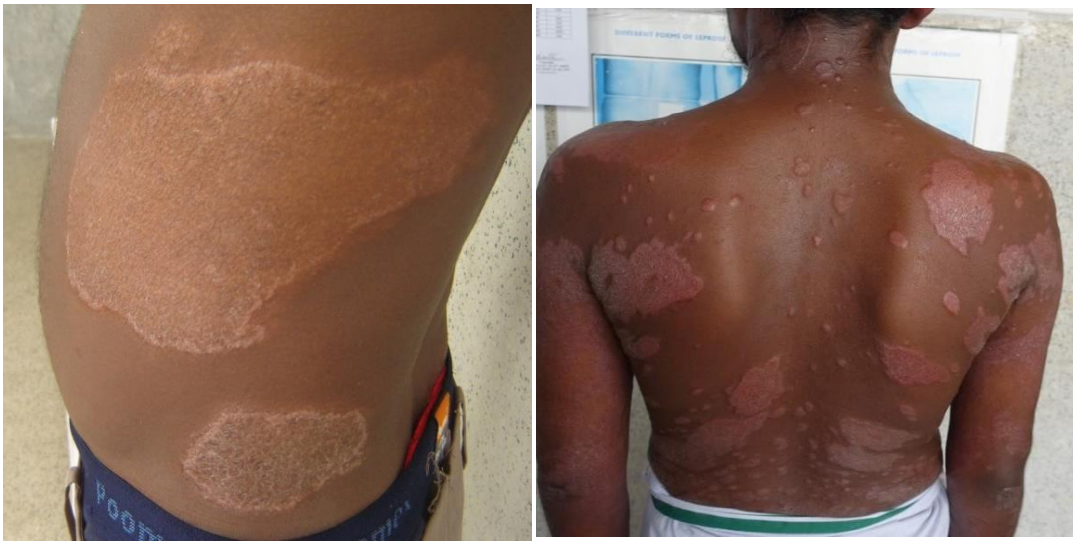
**Inflammation of nerves:** Nerves are frequently affected in Type 1 Reaction.

**Acute Neuritis:** Inflammation of the peripheral nerve results in pain, paresthesia and loss of nerve function - sensory, motor and autonomic. Neuritis may be the only presenting feature of reaction without inflammation in the skin lesions.

**Silent neuropathy / Quiet nerve paralysis:** Nerve function may get affected without any pain or tenderness of the nerve or inflammation of skin lesions. This needs to be identified early and treated promptly.

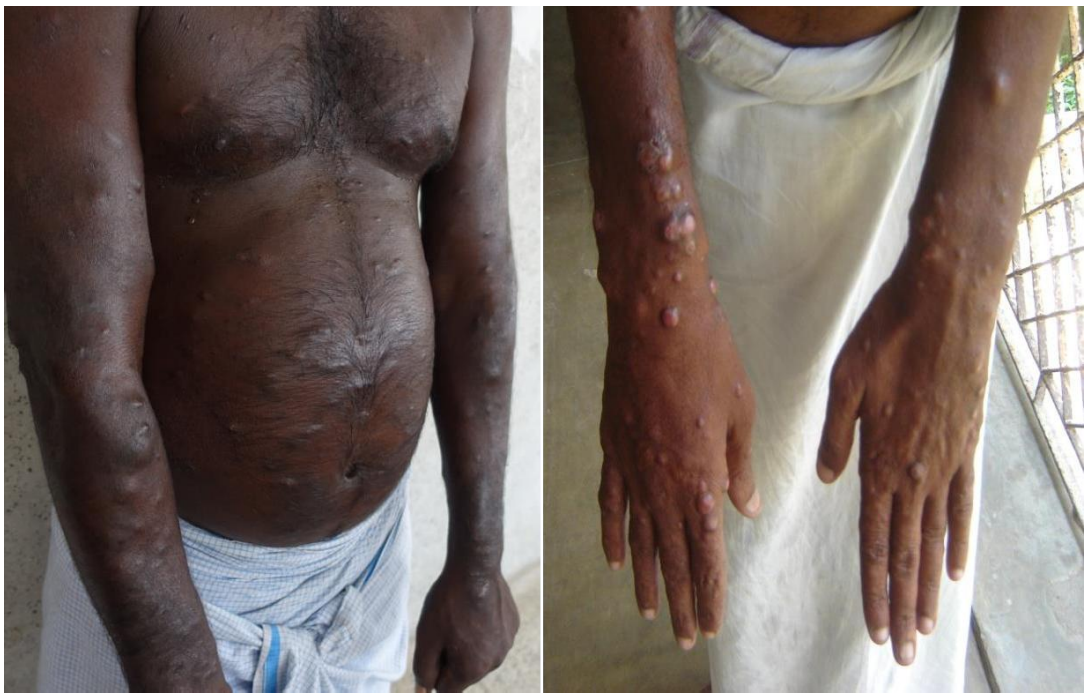
**Swelling of hands and feet:** Swelling of the limbs and/or face may be present as part of Reaction.

**Eyes:** Ocular tissue is not affected in Type 1 Reaction but patient may develop corneal anaesthesia and lagophthalmos due to involvement of trigeminal and facial nerves.



**Type-I Lepra Reaction**

## Type II Lepra Reaction



**Type-II Lepra Reaction**

**Type 2 Lepra Reaction**: Occurs in patients who have a high bacillary load. It is a vasculitis, due to precipitation of immune complexes in multiple organ systems (skin, nerves, testes, eyes, joints, lymph nodes, kidneys, liver, spleen, bone marrow). It may be the presenting complaint of the disease and usually last for few weeks to several months.

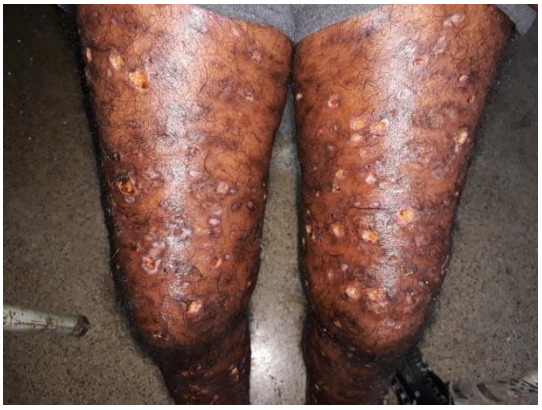
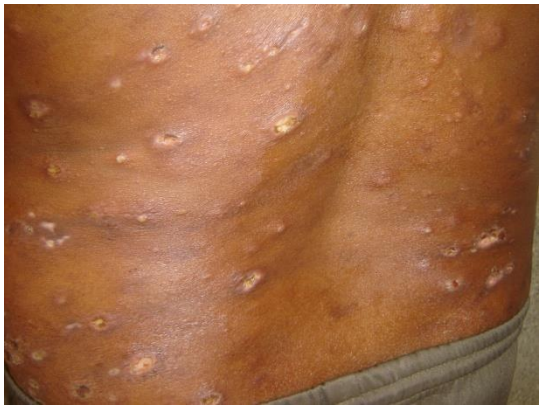
**General condition**: General symptoms like fever, headache and body ache appear before or along with the characteristic nodules that appear on the skin.

**Skin lesions:** Type 2 Reaction exhibits the typical signs of erythema nodosum - red, firm, painful, tender, subcutaneous nodules (about 1-2 cm across) of variable size appear in crops. Nodules blanch on pressure. Usually multiple, they tend to be distributed bilaterally and symmetrically. They appear preferentially on cooler parts of the skin. They usually spare the warmer parts of the body like hairy scalp, axilla, groin and perineum. Rarely they can break down and suppurate / necrose producing Erythema Nodosum Necroticans (ulcerative ENL). These nodule crops are evanescent, melting away in seven to ten days. When nodules fade these leave bluish/brownish marks followed by brownish hue in the skin. Unlike Type-1 Reaction, there is no clinical change in the existing leprosy lesions.

ENL reaction may become chronic and persist for several years causing significant debilitation.

**Eyes:** Ocular tissue may get affected. This may lead to iritis / iridocyclitis (inflammation of the iris and ciliary body), synechiae, glaucoma and impairment of vision. Eye becomes red, watery and painful, pupil becomes constricted and non reactive. Colour of iris becomes dull and patient complains of photophobia (pain in the eye when it is exposed to light). Involvement of eye is an emergency and needs immediate referral to higher centre.

**Swelling of hands, feet and face** may occur.

**ENL Ulcerative reaction**

**Involvement of other organs:** Osteitis-periosteal pain (especially tibia), myositis (muscle pain), Tenosynovitis (pain and swelling of tendons), arthritis, dactylitis, Lymphadenitis, epididymo-orchitis, hepato-splenomegaly, nephritis (proteinuria, RBCs and WBCs in urine), neutrophil leucocytosis and Neuritis.

## Difference between Type-I and Type-II Reactions:

| Features | Type I (Reversal) | Type II (ENL) |
|---|---|---|
| Type of Hypersensitivity | Delayed Hypersensitivity (Type IV) | Antigen antibody reaction (Type III) |
| Skin | Few or many skin lesions suddenly become reddish, swollen, warm (not usually painful and tender).The rest of the skin is normal. | Transient, red, painful, tender, subcutaneous nodules (ENL) appear in groups, commonly on face, arms, legs and are not related to patches |
| Nerves | Acute Neuritis – pain, paresthesia, tenderness, swelling, loss of function (sensory, motor, autonomic) occurs commonly and acutely. | Nerves may be affected but not as common or severe/acute as in Type I |
| General condition | Good, occasionally mild fever | Poor, with fever and general malaise |
| Eye | Lagophthalmos and Corneal anesthesia due to neuritis | Iritis/Iridocyclitis |
| Other Organs | Rarely affected | Other organs like joints, bones, testis, kidney may be affected |

**Management of reaction:** It is very important to reassure the patient and explain that it can be controlled with proper treatment

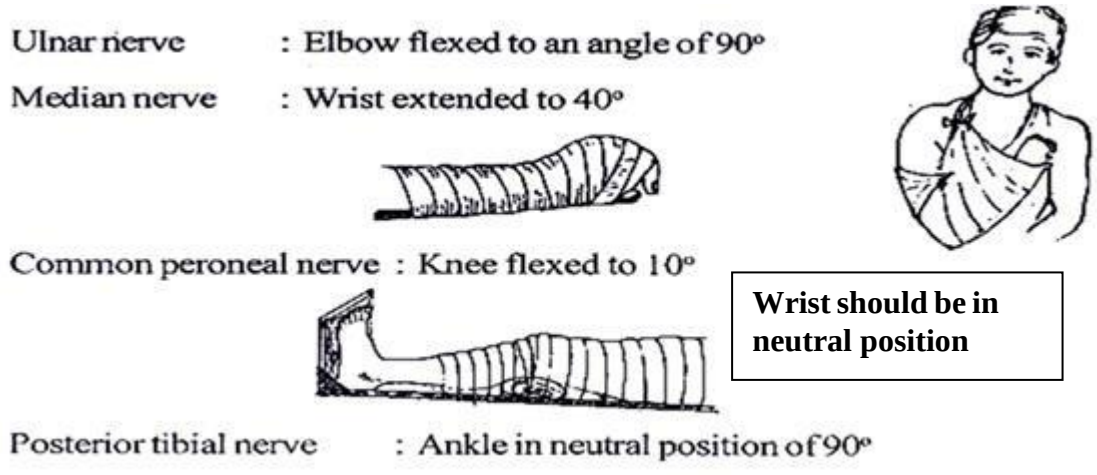
**Type 1 Lepra Reaction:** The patient will need Corticosteroids in addition to rest and analgesics. The drug of choice is Prednisolone. The usual course begins with 40-60 mg daily in single dose preferably in the morning after breakfast (up to a maximum of 1mg/kg of body weight) and the reaction is generally controlled within a few days. The dose is then gradually reduced fortnightly and eventually stopped. Proper precaution should be taken in patients with diabetes, peptic ulcer, hypertension, Tuberculosis etc. Necessary precautions for administering steroid should be taken.

| | |
|---|---|
| **WHO schedule for Prednisolone therapy for patient in Type 1 reaction :** | • 60 mg once daily (preferably in morning at 8 am) for 2 days<br>• 40 mg once daily (preferably in morning at 8 am) for next 2 weeks<br>• 30 mg once daily (preferably in morning at 8 am) for next 2 weeks<br>• 20 mg once daily (preferably in morning at 8 am) for next 2 weeks<br>• 15 mg once daily (preferably in morning at 8 am) for next 2 weeks<br>• 10 mg once daily (preferably in morning at 8 am) for next 2 weeks<br>• 5 mg once daily (preferably in morning at 8 am) for next 2 weeks |

**The prednisolone dose started at 1 mg/kg/day (either 45 or 60 mg/day depending on weight class), and to be tapered down over 20 weeks.**

In case of neuritis, (involvement of peripheral nerve) the period of treatment may be prolonged according to the response. From 20 mg onwards, the period for each dose would be for 4 weeks. Response to steroid therapy is generally seen within two weeks. Review the progress every two weeks. If there is no response the same dose may be continued for further two weeks. If there is good response, the dose may be tapered according to the schedule.

It is also important to provide rest to the affected nerve, if involved, until symptoms subside, by applying a padded splint or any suitable alternative material to immobilize the joints near the affected nerve. The aim is to maintain the limb in the resting position to reduce pain and swelling and prevent worsening of the nerve damage




**Resting position of limbs**

- If a patient develops Lepra Reaction during treatment, do not stop MDT (complete the course of MDT).
- Lepra Reactions, which occur after completion of treatment, should also be managed with steroids as per schedule. MDT should not be started again.

**Type 2 Lepra reaction (ENL):**

In case of reaction not responding to treatment after 4 weeks with prednisolone or at any time showing signs of worsening, the patient should be referred to the nearest referral centre.

| Type 2 Lepra Reaction | Treatment |
|---|---|
| Mild: few nodules, mild fever | Analgesics |
| Severe: severe pain over nodules, tendency for ulceration, high fever, involvement of internal organs | Steroid - Prednisolone course is given in the same dose as for type I reaction, but with faster tapering – given dose not exceeding 2 to 3 weeks |
| Neuritis | Prednisolone regimen as for neuritis in Type 1Reaction |

Clofazimine is also effective for Type 2 Reaction but is less potent than corticosteroids and often takes 4-6 weeks to develop its full effects, so it should never be started as the sole agent for the treatment of recurrent Type 2 reaction. However, clofazimine may be extremely useful for reducing or withdrawing corticosteroids in patients who have become dependent on them. The dose required in such cases is 300 mg daily (maximum of 1 month), which may be given in three divided daily doses to minimize the gastro intestinal side effects. It is tapered gradually to 100 mg daily.

The total duration of clofazimine therapy should not exceed 12 months. Response will be seen after 2 - 4 weeks after starting the drug. Often, Type 2 Reaction may recur due to precipitating causes like infection, stress or helminthic infestation. Lepra reaction may subside faster or less likely to recur if precipitating factor is treated.

For persons who suffer from chronic recurrent ENL reactions not responding to conventional methods of management, Thalidomide is drug of choice. But it is highly teratogenic. Treatment with thalidomide is only recommended in tertiary care hospitals after taking necessary consent. Since this drug is teratogenic, it is contraindicated for use in women of reproductive age group.

Patient has to be followed up every 2 weeks while on steroids – General condition, side effects of steroids and nerve function assessment (NFA).Patient may need referral before starting the steroid therapy or during the treatment if, they have co-morbidities like hypertension, diabetes mellitus, peptic ulcer, tuberculosis, ulcers, and infections**.**

**Pregnant women and children under 12 years require specialist's opinion when prescribing steroids**