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## Supply of basic drugs for the management of leprosy

### Introduction

A questionnaire was sent to ILEP Members and their Field Representatives at the end of 2003 to obtain information about the supply of MDT and prednisolone. This paper incorporates the responses into a summary on the adequacy of the supply of MDT, prednisolone and clofazimine; whether preference for Prednipac or loose prednisolone should be advised; and if the worldwide leprosy requirement for prednisolone can be estimated.

### MDT

Multi-drug treatment (MDT) is the basic treatment for all cases of leprosy. Overall, the supply of WHO MDT blister packs is good. There are sometimes intermittent shortages

of one type of dosage pack, but these are infrequent and usually for a short duration. There is evidence of good co-operation between health workers in the same region sharing resources when shortages occur.

### Prednisolone

Prednisolone is available as loose drug (typically in 5mg tablets) or is supplied in blister packs, as a drug regime of varying (decreasing) doses (Prednipac); it is used in the treatment of reactions and neuritis in leprosy.

Some national programmes have decided that only one form should be available; India has recently advised the use of loose prednisolone tablets.

A comparison of the two forms is given below:

Loose Prednisolone	Prednipac
Less expensive.	More expensive.
Generally easy to purchase locally.	Imported specifically for leprosy, so requirements need to be estimated and procured in advance.
Patients may be confused about their dosage regime, as the number of tablets to be taken changes during the course.	The varying dosages are already included in the packages. The patient always takes one tablet per day.
Dosage and length of course can be easily modified to suit the severity and type of reaction.	Packaging in specific dosages makes it difficult to give a non-standard course.
Some health workers may not have the experience to modify the course appropriately, so that sub-optimal treatment is given.	The standard course may be insufficient in some cases, leading to recurrent reactions.
Health workers often give too low a dose	Sufficiently high dose usually given
Patients experienced with reactions can self-medicate to suit their needs.	Standard dose packs take away patients' control over their own medication.
Health workers are usually aware that prednisolone can be used in other diseases requiring steroids, besides leprosy.	Health workers sometimes think that Prednipacs are just for leprosy patients and treatment of other steroid-responsive diseases may be missed.

*Continued overleaf*

<b>Loose Prednisolone (continued)</b>	<b>Prednipac (continued)</b>
Loose prednisolone may not be as well protected from humidity and more prone to deterioration.	Blister packs give protection from humidity.
Expiry date may be difficult to check.	Expiry date is clearly stated on the pack.
Use of loose prednisolone does not indicate that a person has/had leprosy.	Prednipacs could be stigmatising.
If a family is being treated, it may be difficult to keep children and adult doses separate.	Separate packs are available for children and adults.
Prednisolone is manufactured locally in many countries, including India.	Prednipacs currently have to be imported with all the added complications that this can create.

The Commission advises that the emphasis should be on efficient monitoring of patients for nerve damage so that reactions can be treated early: the use of prednisolone is recommended as effective treatment, whether as Prednipacs or loose prednisolone. ILEP members may be able to assist with the supply of prednisolone, if necessary.

The worldwide requirement for prednisolone is difficult to estimate as:

- The method of treatment of reactions depends on the country; doses of prednisolone and use of additional drugs vary;
- The types of reactions are different, requiring different treatment.

However, the number of new cases reporting with Grade 2 disability can be used as a proxy indicator to estimate prednisolone requirement. This figure is readily available and updated annually. By multiplying this figure by 336 for paucibacillary (PB) cases and 672 for multibacillary (MB) cases, an approximate requirement for the number of 5mg tablets of prednisolone can be estimated. This is based on a 12-week course of prednisolone for PB cases needing treatment and a 24-week course for MB cases, as recommended in ILEP Learning Guide Two: *How to Recognise and Manage Leprosy Reactions*. The use of new cases with Grade 2 disability as a proxy indicator does not imply that all new cases with Grade 2 disability will require treatment with prednisolone.

### **Clofazimine**

Clofazimine is a component of MDT blister packs, but it may also be used on its own, in higher doses, to treat Type 2 reactions in leprosy.

Loose clofazimine is no longer available for purchase from IDA, nor is it readily available from Novartis. However, WHO maintains a stock of clofazimine donated by Novartis for treating severe ENL reactions. As with the MDT donation, WHO provides clofazimine on official government request only to national Ministries of Health or their appointed agents, and not directly to individual institutions, clinics, pharmacies or NGOs who should apply for the drugs through the national programme. Further information can be obtained from the WHO leprosy website <http://www.who.int/lep/> or by contacting Dr S Lyons on [lyonss@who.int](mailto:lyonss@who.int).

Clofazimine is manufactured in India and is widely available there.