

Nilfun[®]

Clotrimazole

COMPOSITION:

Nilfun[®] Cream: Each gram cream contains Clotrimazole USP 10 mg.

PHARMACOLOGY:

Clotrimazole is a broad spectrum antifungal. It also exhibits activity against *Trichomonus*, *Staphylococci*, *Streptococci* and *Bacteroides*.

INDICATION:

The confirmed indication for Nilfun[®] Cream include: 1. all dermatomycoses due to dermatophytes (e.g. *Trichophyton* species). 2. all dermatomycoses due to yeasts (*Candida* species). 3. dermatomycoses due to moulds and other fungi. 4. skin diseases showing superinfections with these fungi. To the dermatomycoses listed under 1-4 belong for example, interdigital mycoses (e.g. athlete's foot), paronychias (associated with nail mycoses), mycoses in skin folds, *Candida* vulvitis, *Candida* balanitis, Pityriasis versicolor, erythrasma.

DOSE & ADMINISTRATION:

Nilfun[®] Cream should be thinly applied 2-3 times daily to the diseased sites and rubbed in. On account of the excellent efficacy, a small amount of cream is usually sufficient for an area about the size of the palm. For the treatment to become a complete success, reliable and sufficiently long application of Nilfun[®] Cream is important. The duration of treatment varies; it depends among other factors on the extent and localisation of the disease.

Recommended duration of treatment:

Dermatomycoses: 3-4 weeks, *Candida* vulvitis and *Candida* balanitis: 1-2 weeks, Erythrasma and Pityriasis versicolor approx.: 3 weeks. In fungal infection of the feet, to prevent relapse, treatment should be continued for about 2 weeks beyond the disappearance of all signs of disease. After washing, the feet should be thoroughly dried (particularly spaces between the toes).

CONTRA-INDICATION:

Hypersensitivity to Clotrimazole.

WARNING AND PRECAUTION:

Nilfun[®] Cream is not for ophthalmic use. If irritation or sensitivity develops with the use of Nilfun[®] Cream treatment should be discontinued and appropriate therapy instituted.

SIDE EFFECTS:

When applied topically, Nilfun[®] Cream is well tolerated. With external application emic effects are not observed. Local irritation or burning sensation may occur in a very few cases but these symptoms are not considered harmful.

USE IN PREGNANCY & LACTATION:

Pregnancy Category B. It is recommended that Clotrimazole should be used in pregnancy only when considered necessary by the physician.

It is not known whether this drug is excreted in human milk, caution should be exercised when clotrimazole is used by a nursing woman.

USE IN CHILDREN & ADOLESCENTS:

Safety and effectiveness in children have been established for Clotrimazole when used as indicated and in the recommended dosage.

DRUG INTERACTION:

No clinically significant interaction have found.

OVERDOSE:

Acute overdosage with topical application of Clotrimazole is unlikely and would not be expected to lead to a life-threatening situation.

STORAGE:

Store in a dry and cool place below 30° C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Nilfun[®] Cream: Each box contains 10 gm cream in a tube.



Manufactured by

Team Pharmaceuticals Ltd.

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