

COMPOSITION

Oxifun[™] lotion: Each gram lotion contains 10 mg of Oxiconazole as Oxiconazole Nitrate INN.

Oxifun[™] cream: Each gram cream contains 10 mg of Oxiconazole as Oxiconazole Nitrate INN.

PHARMACOLOGY

Oxifun™ lotion and cream contains the antifungal active compound Oxiconazole Nitrate. Both formulations are for topical dermatologic use only. Oxiconazole Nitrate is an imidazole derivative whose antifungal activity is derived primarily from the inhibition of ergosterol biosynthesis, which is critical for cellular membrane integrity. It has in vitro activity against a wide range of pathogenic fungi. Oxiconazole has been shown to be active against most strains of the following organisms both in vitro and in clinical infections at indicated body sites: Epidermophyton floccosum, Trichophyton mentagrophytes, Trichophyton rubrum, Malassezia furfur. Oxiconazole exhibits satisfactory in vitro minimum inhibitory concentrations (MICs) against most strains of the following organisms: Microsporum audovini, Microsporum canis, Microsporum gypseum, Trichophyton tonsurans, Trichophyton vioplaceum.

INDICATION

OxifunTM lotion and cream are indicated for the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, or *Epidermophyton floccosum*. **Oxifun**TM is also indicated for the topical treatment of tinea (pityriasis) versicolor due to *Malassezia furfur*.

DOSAGE AND ADMINISTRATION

Oxifun[™] lotion and cream should be applied to affected and immediately surrounding areas once to twice daily in patients with tinea pedis, tinea corporis, or tinea cruris. **Oxifun**[™] should be applied once daily in the treatment of tinea (pityriasis) versicolor & tinea corporis for 2 weeks and tinea pedis for 1 month to reduce the possibility of recurrence.

CONTRAINDICATION

Oxiconazole is contraindicated in individuals who have shown previous hypersensitivity to Oxiconazole.

SIDE EFFECT

Pruritus, burning, irritation and allergic contact dermatitis, folliculitis, erythema, and papules, fissure, maceration, rash, stinging and nodules.

DRUG INTERACTION

Potential drug interactions between Oxiconazole and other drugs have not been systemically evaluated.

PRECAUTION

These preparations are not for ophthalmic or intravaginal use.

INFORMATION FOR PATIENT

- . Use Oxiconazole Nitrate as directed by the physician. The hands should be washed after applying the medication to the affected area(s). Avoid contact with the eyes, nose, mouth, and other mucous membranes. Oxiconazole Nitrate is for external use only.
- . Use the medication for the full treatment time recommended by the physician, even though symptoms may have improved.

 Notify the physician if there is no improvement after 2 to 4 weeks or sooner if the condition worsens. Inform the physician if the area of application shows signs of increased irritation, itching, burning, blistering, swelling, or oozing.
- . Avoid the use of occlusive dressings unless otherwise directed by the physician.
- . Do not use this medication for any disorder other than that for which it was prescribed.

USE IN PREGNANCY AND LACTATION

Pregnancy category B.

Because Oxiconazole Nitrate is excreted in human milk, caution should be exercised when the drug is administered to a nursing woman.

STORAGE

Store below 25°C. Protect from light. Do not freeze.

HOW SUPPLIED

Oxifun[™] lotion: Each bottle contains 30 ml lotion.

Oxifun™ cream: Each laminated tube contains 10 gram cream.

Manufactured by

