

COMPOSITION

Clopirox™ Cream: Each gram cream contains Ciclopirox Olamine USP 10 mg.

PHARMACOLOGY

Ciclopirox Olamine is a synthetic broad spectrum antifungal agent that inhibits the growth of pathogenic dermatophytes, yeasts, and Malassezia furfur. Ciclopirox Olamine exhibits fungicidal activity in vitro against isolates of *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum*, *Microsporum canis*, and *Candida albicans*. The mode of action of Ciclopirox Olamine was studied mainly in Candida albicans. It is presumed that Ciclopirox Olamine mediated growth inhibition or death of fungal cells is primarily caused by in vitro cellular depletion of some essential substrates and/or ions and that such effects are brought about through blockage of their uptake from the medium. In addition to its broad spectrum of antifungal action, Ciclopirox also exerts antibacterial activity against many Gram-positive and Gram-negative bacteria. The anti-inflammatory effects of Ciclopirox have been demonstrated in human polymorphonuclear cells, where Ciclopirox has inhibited the synthesis of prostaglandin and leukotriene. Ciclopirox can also exhibit its anti-inflammatory effects by inhibiting the formation of 5-lipoxygenase and cyclooxygenase.

INDICATION

Clopirox™ Cream is indicated for the topical treatment of the following dermal infections: Tinea pedis, Tinea cruris and Tinea corporis due to Trichophyton rubrum, Trichophyton mentagrophytes, Epidemophyton floccosum and Microsporum canis, candidiasis (moniliasis) due to Candida albicans, and Tinea (pityriasis) versicolor due to Malassezia furfur. Clopirox™ Cream is also highly effective against some gram negative & some gram positive bacteria. Owing to its anti-inflammatory effects, Ciclopirox Olamine alone is sufficient to treat mild to moderate inflammatory fungal infections.

DOSAGE AND ADMINISTRATION

Clopirox™ Cream should be gently massaged onto the affected and surrounding skin areas twice daily for four weeks. Clinical improvement with relief of pruritus and other symptoms usually occurs within the first week of treatment. If a patient shows no clinical improvement after four weeks of treatment with Clopirox™ cream, the diagnosis should be redetermined. Patients with Tinea versicolor usually exhibit clinical and mycological clearing after two weeks of treatment.

CONTRAINDICATION

Ciclopirox Olamine cream is contraindicated in individuals who have shown hypersensitivity to any of its components.

ADVERSE REACTIONS

Ciclopirox Olamine cream is well tolerated with a low incidence of adverse reactions reported in clinical trials.

PRECAUTION

Ciclopirox Olamine cream is not for ophthalmic use.

USE IN PREGNANCY

Pregnancy category B.

USE IN NURSING MOTHER

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk. caution should be exercised when Ciclopirox Olamine cream or is administered to nursing women.

USE IN CHILDREN

Safety and effectiveness in children below the age of 10 years have not been established.

STORAGI

Store below 25°C, protect from light. Keep out of the reach of children.

HOW SUPPLIED

Clopirox™ Cream: Each pack has an aluminium tube containing 15 gm cream.

Manufactured by

