

Ciclopirox[™] Shampoo

Ciclopirox Olamine USP 1%

COMPOSITION

Ciclopirox[™] Shampoo: Each gram Shampoo 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

Ciclopirox[™] Shampoo is indicated in the treatment of Seborrheic dermatitis, Dandruff, Inflammation and Swelling of the scalp.

DOSAGE AND ADMINISTRATION

Wet hair and apply approximately 1 teaspoon (5 ml) of **Ciclopirox**[™] Shampoo (Ciclopirox Olamine Shampoo) to the scalp. Up to 2 teaspoons (10 ml) may be used for long hair. Lather and leave on hair and scalp for 3 minutes. A timer may be used. Avoid contact with eyes. Treatment should be repeated twice per week for 4 weeks, with a minimum of 3 days between applications.

CONTRAINDICATION

This Shampoo is contraindicated in individuals who have shown hypersensitivity to any of its components.

ADVERSE REACTIONS

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

PRECAUTION

Ciclopirox Olamine Shampoo is not for ophthalmic, oral, or intravaginal 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 Shampoo or is administered to nursing women.

USE IN CHILDREN

No clinical trials have been conducted in subjects younger than 16 years.

STORAGE

Keep away from light and moisture. Store below 30°C. Keep out of the reach of children.

HOW SUPPLIED

Ciclopirox[™] Shampoo: Each container contains 100 ml Ciclopirox Olamine Shampoo.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
Salgaria, Pabna, Bangladesh

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