

CandiroxTM Nail Lacquer

Ciclopirox 8%

Presentation

CandiroxTM Nail Lacquer: Each gram solution contains Ciclopirox BP 80 mg.

Description

Ciclopirox is a synthetic antifungal agent. Ciclopirox Nail Lacquer is a clear, colorless to slightly yellowish solution. It is intended for topical use on fingernails and toenails and immediately adjacent skin. In contrast to the azoles and other antimycotic drugs, the mechanism of action of Ciclopirox is poorly understood. However, loss of function of certain catalase and peroxidase enzymes of fungi has been implicated as the mechanism of action, as well as various other components of cellular metabolism.

Indications and Uses

Ciclopirox Nail Lacquer is indicated as topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails (without lunula involvement) due to *Trichophyton rubrum*.

Dosage and Administration

1. Before starting treatment, any loose nail or nail material should be removed using nail clippers or nail files. If one has diabetes or problems with numbness in toes or fingers, he/she should talk to the health care provider before trimming the nails or removing any nail material.
2. Ciclopirox Nail Lacquer should be applied evenly over the entire nail plate once daily (preferably at bedtime or eight hours before washing) to all affected nails with the applicator brush provided. If possible, it should be applied to the underside of the nail and to the skin beneath it. The nail lacquer should be allowed to dry approximately 30 seconds before putting on socks or stockings.
3. Ciclopirox Nail Lacquer should be applied daily over the previous coat.
4. Once a week, Ciclopirox Nail Lacquer should be removed with alcohol pad (nail polish remover). Using scissors, nailclippers, or nail files, the damaged nail should be removed as much as possible.
5. This cycle (steps 2 through 4) should be repeated throughout the duration of therapy (6 months to 48 weeks).

Side Effects

Commonly redness/burning of treated skin or changes in shape/color of nail may occur. Very serious allergic reaction to Ciclopirox is rare.

Precautions

If a reaction suggesting sensitivity or chemical irritation occurs with the use of Ciclopirox Nail Lacquer, treatment should be discontinued. So far there is no relevant clinical experience with patients with insulin dependent diabetes or who have diabetic neuropathy. The risk of removal of the unattached, infected nail should be carefully considered before prescribing to patients with a history of insulin dependent diabetes mellitus or diabetic neuropathy.

Use in Pregnancy and Lactation

Pregnancy: Pregnancy Category B. There are no adequate or well-controlled studies of topically applied ciclopirox in pregnant women. Ciclopirox Nail Lacquer should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: It is not known whether this drug is excreted in human milk. Since many drugs are excreted in human milk, caution should be exercised when Ciclopirox Nail Lacquer is administered to a nursing woman.

Use in Children

Ciclopirox Nail Lacquer is considered safe for use in children of 12 years and older. No clinical trials have been conducted in the pediatric population.

Warnings

Ciclopirox Nail Lacquer is not for ophthalmic, oral, or intravaginal use. For use on nails and immediately adjacent skin only.

Contraindications

Ciclopirox Nail Lacquer is contraindicated in individuals who have shown hypersensitivity to any of its components.

Drug Interactions

No studies have been conducted to determine whether Ciclopirox might reduce the effectiveness of systemic antifungal agents for onychomycosis. Therefore, the concomitant use of Ciclopirox 8% topical solution and systemic antifungal agents for onychomycosis is not recommended.

Storage Condition

Do not store above 30° C. Protect CandiroxTM Nail Lacquer from heat. Keep the bottle tightly closed. Keep away from light and out of the reach of children.

Commercial Pack

CandiroxTM Nail Lacquer: Each box contains 1 bottle of 3.3 ml nail lacquer, 16 alcohol pad & 8 nail files.