

(Tioconazole)
1% Dermal Cream / Vaginal Suppository

DESCRIPTION

Tioconazole is a member of the imidazole class of antifungal agents. Although the mode of action of tioconazole has not as yet been determined, several studies have demonstrated that the imidazoles inhibit ergosterol synthesis in fungi by blocking C-14 demethylation. As a result, there is an accumulation of C-14 methyl sterol intermediates like Lanosterol, and a decrease in ergosterol. Lanosterol cannot support yeast growth in the absence of ergosterol, and the inhibition of ergosterol synthesis or the accumulation of Lanosterol may be the primary antifungal mechanism of this class of drugs. At high drug concentrations the imidazoles have been postulated to exert a fungicidal effect by rapid membrane damage of the fungi. Tycon has been shown to have a broad spectrum of activity against dermatophytes and yeasts, as well as against some chlamydia, trichomonads and Gram-positive bacteria.

COMPOSITION

Cream: Each gram contains Tioconazole BP 10 mg.
Vaginal suppository: Each Vaginal suppository contains Tioconazole BP 300 mg.

INDICATIONS

1. Fungal infection of skin: Dermatophyte infections including tinea corporis, tinea cruris, tinea manuum, tinea pedis, pityriasis versicolor (tinea versicolor), dermal candidiasis

2. Erythrasma

Its activity against some Gram-positive bacteria is an added benefit in mixed infections.

3. Vulvo-vaginal candidiasis (VVC) .

DOSAGE AND ADMINISTRATION

TYCON (Tioconazole) cream should be gently massaged into the affected and surrounding skin. Treatment may be once or twice daily in the morning and/ or evening. Duration of treatment will depend on infecting organism and site of infection. Up to 6 weeks may be required for chronic hyperkeratotic tinea pedis.

Dermatophyte infections at other sites, candidiasis, and erythrasma usually require 2 to 4 weeks treatment. In majority of patients with pityriasis versicolor 7 days treatment is sufficient to achieve a cure.

One 300 mg suppository intravaginally as single dose, preferably at bedtime; for patients who are improved but not completely cured a repeat application may be effective if administered one week later.

Vaginal candidiasis may be accompanied by vulval infection. Therefore, concomitant local treatment with the Tioconazole cream should be applied to the vulva and as far as the anal region once or twice daily is advisable. A small amount of the cream should be gently rubbed onto the irritated area, moving from front to back for up to 7 days as needed. In vulvovaginal candidiasis concomitant topical treatment of consort(s) is not necessary unless candidal dermatitis of the penis is present. To treat the male partner, a small amount of cream should be applied onto the glans penis once or twice daily for up to 7 days as needed or to help to prevent reinfection by the partner.

Or as directed by the physician.

CONTRAINDICATIONS

It is contraindicated in individuals who have been shown to be hypersensitive to imidazole antifungal agents, or to any of the components of the cream.

SIDE EFFECTS

The most frequently observed local side effects are burning (6%) and itching (5%). Isolated local vaginal symptoms such as irritation, discharge, labial swelling, swelling, vaginal pain, dysuria, nocturia, dyspareunia, dryness of vaginal secretions, vulva edema are observed.

PRECAUTIONS

If a sensitivity reaction develops with the use of Tioconazole, treatment should be discontinued.

Constituents of the vaginal suppository may be incompatible with rubber in both contraceptive condoms and diaphragms. Skin and mucosal sensitization may occur. If so, use of tioconazole vaginal suppository should be discontinued.

USE IN PREGNANCY AND LACTATION

There is insufficient evidence as to the drug's safety in human pregnancy and lactation and it should therefore be avoided.

SUPPLY

Tycon Cream: Each tube contains 10 gm of 1% Tioconazole cream.

Tycon Vaginal Suppository: Each box contains 1×5 suppositories in blister strip.

Store in a cool and dry place, protected from light. Keep all medicines out of reach of children.

*Further information is available on request.

FOR HEALTH, VIGOUR AND HAPPINESS

labhamrai, Dhaka, Bangladesh.