DERMOZOLE CREAM

(Isoconazole Nitrate 10 mg/g - 1% w/w)

COMPOSITION

Each gram of cream contains Isoconazole Nitrate 10 mg (1% w/w). Excipients q.s. The final excipient composition should correspond to the approved product formula.

DESCRIPTION

Dermozole is a topical antifungal cream intended for external application to the skin.

PHARMACOLOGY

Isoconazole nitrate is an imidazole antifungal agent with broad activity against dermatophytes, yeasts, yeast-like fungi and moulds. It is also active in vitro against certain Gram-positive organisms, including the causative organism of erythrasma. Isoconazole penetrates the skin following topical application; systemic absorption is low.

INDICATIONS

Treatment of superficial fungal infections of the skin, including tinea pedis (athlete's foot), tinea manuum (hands), tinea cruris (groin), fungal infections of the genital region and erythrasma.

Genital-region treatment should be under medical advice.

DOSAGE AND ADMINISTRATION

For cutaneous use only. Apply a thin layer to the affected skin once daily, or as directed by the physician. Treatment is generally continued for 2-3 weeks and may require 4 weeks for persistent infections, particularly between the toes. To help avoid recurrence, continue for at least 2 weeks after clinical healing, as advised by the physician.

METHOD OF USE

Clean and dry affected areas before application, especially between toes. Wash hands after applying unless the hands are being treated. Use regularly for the prescribed duration. If a dose is missed, apply when remembered unless close to the next application; do not double the amount.

CONTRAINDICATIONS

Hypersensitivity to isoconazole nitrate or to any component of the formulation.

WARNINGS AND PRECAUTIONS

For external use only. Avoid contact with eyes; if accidental contact occurs, rinse thoroughly with water. Stop treatment and seek medical advice if marked irritation or allergic reaction occurs. Maintain proper hygiene and keep affected areas clean and dry. Change socks and towels frequently to reduce recurrence.

SPECIAL PRECAUTIONS

When used in the genital region, cream formulations containing mineral oil or paraffin may reduce the reliability of latex condoms and diaphragms. This precaution depends on the actual excipients in Dermozole; consult the approved product composition.

DRUG INTERACTIONS

No formal drug-interaction studies have been performed for topical isoconazole. Tell your physician or pharmacist about other medicines applied to the affected skin.

PREGNANCY

Available experience with topical isoconazole has not suggested a teratogenic risk in humans. Use during pregnancy, especially the first trimester, only after medical assessment of potential benefit and risk.

LACTATION

It is unknown whether isoconazole is excreted in human milk. Use during breastfeeding only after medical assessment. Do not apply to the breast area during breastfeeding.

PEDIATRIC USE

Limited pediatric data are available; a general pediatric dosage recommendation has not been established. Use in children only under medical guidance.

GERIATRIC USE

No specific age-related dosage adjustment is established for topical application. Use as directed by the physician.

ADVERSE REACTIONS

Common: burning or irritation at the application site. Uncommon: itching, dryness, eczema, dyshidrosis or contact dermatitis. Rare: localized swelling and skin fissures. Redness, blisters and allergic skin reactions have also been reported. Seek medical advice if reactions are severe or persistent.

OVERDOSAGE

Acute intoxication from a single excessive application is unlikely. In case of accidental ingestion, contact a healthcare professional for advice. Do not induce vomiting unless specifically instructed.

EFFECT ON DRIVING AND MACHINERY

No impairment of driving or machine operation has been observed with topical isoconazole.

STORAGE

Keep tightly closed and out of reach of children. Protect from excessive heat. Follow the temperature limit and in-use shelf life stated on the approved product label.

PRESENTATION

Dermozole Cream: 10 g tube.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.