DIFZOLE CREAM

(Isoconazole Nitrate 1% +
Diflucortolone Valerate 0.1%)

COMPOSITION

Each gram of cream contains:
Isoconazole Nitrate 10 mg (1% w/w).
Diflucortolone Valerate 1 mg (0.1% w/w).
Cream base: q.s. according to the approved formulation.

DESCRIPTION

Difzole is a combination topical antifungal and corticosteroid cream for application to the skin.

PHARMACOLOGY

Isoconazole nitrate is an imidazole antimycotic with activity against dermatophytes, yeasts, yeast-like fungi and some other microorganisms associated with superficial skin infections. Diflucortolone valerate is a potent topical corticosteroid that reduces inflammation, redness, itching, burning and other symptoms of inflammatory skin disorders.

INDICATIONS

Initial or interim treatment of superficial fungal skin infections associated with pronounced inflammatory or eczematous changes, including affected areas of the hands, between fingers or toes, groin and genital region.

DOSAGE AND ADMINISTRATION

For cutaneous use only. Apply a thin layer to affected skin twice daily or as prescribed. Wash hands before and after use, unless the hands are being treated.

Duration: Stop this combination when inflammation has resolved and, in any event, no later than 2 weeks. Continue antifungal therapy, when needed, with a corticosteroid-free antifungal preparation. This is particularly important in groin and genital areas.

CONTRAINDICATIONS

Do not use in patients with hypersensitivity to isoconazole nitrate, diflucortolone valerate or any ingredient of the cream. Do not apply to skin affected by tuberculosis, syphilis, viral infections (such as chickenpox, shingles or herpes), rosacea, perioral dermatitis or post-vaccination skin reactions.

WARNINGS AND PRECAUTIONS

Avoid contact with the eyes. Do not apply to the face near the eyes. Treatment of large skin areas, prolonged use or application beneath airtight dressings increases corticosteroid absorption and may result in local or systemic adverse effects, including glaucoma when used near the eyes.

Do not use under occlusive dressings unless specifically directed. Appropriate additional treatment is needed if a bacterial skin infection is also present. Maintain good hygiene and keep affected areas clean and dry.

Use in the genital area may impair the reliability of latex condoms or diaphragms if the formulation contains paraffin-based excipients; consult the product excipient list and consider alternative protection.

PEDIATRIC USE

Published reference formulations do not require dose adjustment for children aged 2 years and over; safety data are limited in children younger than 2 years. Use in children only under medical advice, over the smallest area and shortest necessary duration.

DRUG INTERACTIONS

No formal interaction studies have been performed for the reference combination. Inform the prescriber about other topical products applied to the same region.

PREGNANCY

Use of topical corticosteroids should generally be avoided during the first trimester. If treatment is considered necessary in pregnancy, weigh benefits against potential fetal risks. Avoid prolonged treatment, large areas and occlusive dressings.

LACTATION

It is not known whether the active ingredients are excreted in human milk after topical application. Do not apply to the breasts while breastfeeding. Avoid treating large areas, prolonged use and occlusion.

ADVERSE REACTIONS

Local adverse reactions may include irritation, burning, itching, redness, dryness or allergic contact dermatitis. Prolonged, excessive or occluded application of topical corticosteroids may cause skin thinning (atrophy), stretch marks, telangiectasia, acne-like changes, changes in pigmentation, secondary infection or systemic corticosteroid effects.

Report severe irritation, allergic reactions or unexpected visual disturbances to a healthcare professional.

EFFECTS ON DRIVING

No meaningful effect on driving or operation of machinery is expected from correct topical use.

OVERDOSAGE

Acute toxicity is unlikely after a single excessive skin application. If accidentally swallowed, seek medical advice. Excessive repeated application may produce corticosteroid-related adverse effects; consult a physician.

STORAGE CONDITIONS

Store below 30°C, protected from excessive heat and direct sunlight. Keep the tube closed and out of the reach of children. Do not use after the expiry date.

PRESENTATION

Difzole Cream: 10 g tube.

IMPORTANT INSTRUCTIONS

For external use only. Avoid application to the eyes and mucous membranes. Use only as directed by a healthcare professional. If symptoms persist or worsen, seek medical advice.

THERAPEUTIC CATEGORY

Topical antifungal with corticosteroid.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.