ZAMITRO-H CREAM

Clotrimazole 1% w/w + Hydrocortisone 1% w/w
For external use only

COMPOSITION

Each 1 g of cream contains Clotrimazole 10 mg (1% w/w) and Hydrocortisone 10 mg (1% w/w) in a suitable cream base.

PHARMACOLOGICAL CLASS

Topical imidazole antifungal combined with a mild topical corticosteroid. Therapeutic segment: Dermatology.

DESCRIPTION

A topical combination for fungal skin infection accompanied by inflammation. Clotrimazole treats susceptible fungi; hydrocortisone temporarily reduces associated redness, itching and swelling.

PHARMACOLOGY

Clotrimazole inhibits fungal ergosterol synthesis, impairing cell-membrane function. Hydrocortisone binds glucocorticoid receptors and suppresses inflammatory mediator activity. Systemic absorption may increase on damaged skin, large treated areas, prolonged use or under occlusion.

INDICATIONS

Short-term treatment of inflamed superficial fungal skin infections caused by susceptible organisms, when an antifungal and mild corticosteroid are both clinically indicated, such as inflamed tinea pedis, tinea cruris or tinea corporis. Use only for indications approved for the registered product.

DOSAGE AND ADMINISTRATION

Adults and adolescents: clean and dry the affected area; apply a thin film gently to affected skin, usually twice daily, or as directed by the prescriber. Wash hands after application unless hands are treated. Use the combination for the shortest necessary period; generally do not exceed 7 days without medical reassessment. If fungal infection persists after inflammation settles, continue an appropriate antifungal alone as directed.

METHOD OF APPLICATION

Apply only to the affected skin. Avoid eyes, mouth, mucous membranes, and intravaginal use. Do not apply under airtight dressings unless specifically directed. Keep skin folds clean and dry; avoid sharing towels or clothing.

CONTRAINDICATIONS

Hypersensitivity to clotrimazole, hydrocortisone, other imidazole antifungals or any excipient. Do not use on untreated bacterial or viral skin infections (including herpes simplex, chickenpox), tuberculosis-related skin lesions, or other conditions for which topical corticosteroids are contraindicated.

WARNINGS AND PRECAUTIONS

The steroid can mask or worsen infection and may delay recognition of treatment failure. Do not use for acne, rosacea, perioral dermatitis or undiagnosed rashes. Avoid application to broken skin, extensive areas, face or genital skin unless prescribed. Prolonged or excessive use may cause skin thinning, striae, telangiectasia, pigment changes and systemic corticosteroid effects. Stop and seek medical advice if irritation, sensitization or worsening infection occurs.

CHILDREN

Use in children only on medical advice. Children are more susceptible to systemic corticosteroid absorption and adrenal suppression, particularly with large areas, prolonged use or occlusive diapers. Avoid routine use in infants.

DRUG INTERACTIONS

Clinically important interactions are uncommon with limited topical use. Concurrent use of other irritating skin preparations or topical corticosteroids may increase adverse effects. Inform the prescriber about other topical treatments.

PREGNANCY

Use only if clearly needed and on medical advice. Avoid extensive application, occlusion and prolonged courses. Although topical exposure is generally limited, systemic corticosteroid absorption is possible.

LACTATION

Use cautiously on medical advice. Do not apply to the breast or nipple before feeding; prevent infant contact with treated areas.

ADVERSE REACTIONS

Local burning, stinging, itching, irritation, redness, dryness, rash or contact dermatitis may occur. Corticosteroid-related effects with excessive use include skin atrophy, striae, telangiectasia, folliculitis, acneiform eruption, altered pigmentation and secondary infection. Rare systemic corticosteroid effects may occur with extensive or prolonged application.

OVERDOSAGE

Acute overdose from limited topical application is unlikely. Excessive or prolonged application may increase corticosteroid absorption. Discontinue inappropriate use and seek medical assessment if signs of systemic effects occur. In case of accidental ingestion, seek medical advice promptly.

WHEN TO SEEK MEDICAL ADVICE

Seek assessment if symptoms worsen, spread, recur, or fail to improve within approximately 7 days; if there is pus, fever, marked pain or extensive infection; or if the diagnosis is uncertain. Do not continue steroid-containing treatment indefinitely.

STORAGE

Store according to the temperature and conditions stated on the approved carton and label. Keep container tightly closed. Protect from excessive heat. Keep out of reach of children. Do not use after the expiry date.

PRESENTATION

Zamitro-H Cream: 10 g tube. Each gram contains Clotrimazole 10 mg and Hydrocortisone 10 mg.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.