

Cream Travozol

(Isconazole nitrate + Diflucortolone Valerate)

COMPOSITION

Each gram contains:
Isconazole nitrate.....10mg
Diflucortolone Valerate.....1mg
(Innovator's specifications)

DESCRIPTION

Travozol cream contains isconazole nitrate and diflucortolone valerate, an imidazole and triazole derivatives combination. Isoconazole is an imidazole antifungal used for superficial skin infections. Diflucortolone is a topical corticosteroid used for the symptomatic treatment of inflammatory skin disorders like eczema, seborrheic eczema, lichen planus and psoriasis.

MECHANISM OF ACTION

Isoconazole is an azole antifungal drug that has similar effectiveness to clotrimazole in the different kind of infections. Isoconazole nitrate used in combination with corticosteroid diflucortolone to increase its bioavailability. Diflucortolone performs its action by the induction of lipocortins which are phospholipase A2 inhibitory proteins and sequentially inhibiting the release of arachidonic acid. The absence of arachidonic acid translates to the inhibition of the formation, release and activity of endogenous chemical inflammatory mediators.

INDICATIONS

Isoconazole nitrate/diflucortolone cream is indicated in initial or interim treatment of those superficial fungal infections of the skin which are accompanied by highly inflammatory or eczematous skin conditions, e.g. in the region of the hands, the interdigital spaces of the feet and in the inguinal and genital regions.

DOSAGE & ADMINISTRATION

Isoconazole nitrate/diflucortolone cream should be applied twice daily to the diseased areas of skin. Treatment must be terminated after regression of the inflammatory or eczematous skin conditions or at the latest after 2 weeks and therapy continued or followed up with a glucocorticoid-free anti-fungal preparation. This applies in particular for use in the inguinal and genital regions.

Pediatric population:

Dose adjustments are not required when Travozol is administered to children aged 2 years or older and adolescents.

Only limited data on the safety of Travozol in children aged below 2 years are available.

PHARMACOKINETICS

Isoconazole quickly passes from the cream into the skin. At the latest after 1 hour, the maximum concentrations of active substance are reached in all skin layers. Isoconazole is not inactivated by

ٹراوازول کریم

(آئسکانازول نائٹریٹ + ڈیفلوکورٹولون ولیٹریٹ)

metabolism in the skin. The systemic load resulting from percutaneous resorption is low. The active substance that reaches the body through the skin is metabolised completely and eliminated rapidly, 33% by renal route and 66% by bile duct. Diflucortolone valerate also quickly passes from the cream into the skin. Peak concentrations in the stratum corneum were measured after 1 hour. Diflucortolone valerate undergoes only slight hydrolysis in the skin, so that the active substance absorbed into the skin is totally active locally. After exposure for 4 hours, less than 1% of the amount of corticosteroid from the cream is resorbed. In the body, diflucortolone valerate is rapidly split into diflucortolone and valeric acid. Valeric acid is incorporated into the metabolism of fatty acids.

WARNINGS & PRECAUTIONS

- Specific additional therapy is required for bacterial infections of the skin.
- Isoconazole nitrate/diflucortolone cream should not be allowed to come into contact with the eyes when being applied to the face. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.
- Extensive application of topical glucocorticoids to large areas of the body or for prolonged periods of time, in particular under occlusion, may increase the risk of systemic side effects.
- As known from systemic glucocorticoids, glaucoma may also develop from using local glucocorticoids (e.g. after large-dosed or extensive application over a prolonged period, occlusive dressing techniques, or application to the skin around the eyes).
- The physician should advise the patients on hygienic measures during the treatment.
- If this cream is applied to the genital regions, the excipients liquid paraffin and soft paraffin may cause damage of latex products for barrier methods such as condoms and diaphragms used concomitantly, thus impairing their effectiveness.
- This medicinal product contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Pregnancy

There are no data from the use of isconazole nitrate/diflucortolone valerate in pregnant women. It must be avoided during the first trimester of pregnancy. In particular, treating large areas, prolonged use or occlusive dressings should be avoided during the whole of pregnancy. Epidemiological studies suggest that there could possibly be an increased risk of oral clefts among newborns of women who were treated with glucocorticoids during the first

trimester of pregnancy.

Lactation

It is unknown whether isconazole nitrate/diflucortolone valerate are excreted in human milk. A risk to the suckling child cannot be excluded. Nursing mothers should not be treated on the breasts. Treating large areas, prolonged use or occlusive dressings should be avoided during lactation. The clinical indication for treatment with isconazole nitrate/diflucortolone must be carefully reviewed and the benefits weighed against the risks in lactating women.

SIDE EFFECTS

As with other glucocorticoids for topical application, the following local adverse reactions may occur (frequency not known): Skin atrophy, application site folliculitis, hypertrichosis, telangiectasia, perioral dermatitis, skin discolorations, acne, and/or allergic skin reactions to any of the ingredients of the formulation. Systemic effects due to absorption may occur when topical preparations containing glucocorticoids are applied. Adverse reactions cannot be excluded in neonates whose mothers have been treated extensively or for a prolonged period of time during pregnancy or while lactating (for example, reduced adrenocortical function, and immunosuppression).

CONTRAINDICATIONS

Travozol cream is contraindicated in tuberculous or syphilitic processes in the area to be treated, virus diseases (e.g. varicella, herpes zoster), rosacea, perioral dermatitis and post vaccination skin reactions in the area to be treated. Hypersensitivity to the active substances or to any of the excipients. In general, Travozol should be used without occlusion.

STORAGE & INSTRUCTIONS

Do not store above 30°C. Do not refrigerate or freeze. Protect from heat, sunlight and moisture. Keep away from the reach of the children.

To be sold on the prescription of a registered medical practitioner only.

For external use only.

HOW SUPPLIED

Travozol Cream: 10g

خوراک و طریقہ استعمال:

متاثرہ حصے پر دن میں دو بار لگانیں یا ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۳۰ گری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں۔
ریفریجریٹر میں نہ رکھیں۔
دھوپ، گرمی، نمی اور تھمد ہونے سے بچائیں۔
پچول کی تیغ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔
صرف بیرونی استعمال کے لئے ہے۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

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Lahore, Pakistan.