



KETOCONAZOLE 2%

Topical cream



Pharmacological information:

KETOCONAZOLE 2% CREAM treats the affection of tinea of the feet, hands, crotches, perianal area and body. Dermatophytosis caused by *Trichopyton* sp, *Microsporum* sp and *Epidermophyton* sp.

Composition: Each 100 g contain:

Ketoconazole.....2 g
Excipients q.s.

Dose: Apply thin layer of cream on the affected area once or twice a day or according to medical prescription.

Precautions: No data was found in relation to the use of ketoconazol during pregnancy. Since it is not absorbed after topical application, it is not contraindicated. As a precaution, it is better to avoid using it during pregnancy and nursing.

Contraindications: Hypersensitivity to any of the components. Patients who have a history of alcoholism or hepatic diseases, since the subjacent hepatocellular injuries can be exacerbated due to the use of ketoconazole.

Secondary effects: Changes on hair texture, scalp blisters, dry skin, itching, oily or dry hair and scalp, irritation, itching on the area where the medicament was applied.

Pharmacological interactions: Anticoagulants (warfarine): increase in plasmatic levels of anticoagulant (hemorrhage risk). Tricyclic antidepressants: increase in the plasmatic levels of the antidepressant, with a possible potentialization of its action. Antiepileptics (phenobarbital, phenytoin), antiulcerants (cimetidine, omeprazole), didanosine, rifampicin: decrease the antifungal in plasma. Antivirals (indinavir, nelfinavir), astemizole, benzodiazepines, corticosteroids, cyclosporine, cisapride, loratadine, propafenone, quinidine, terfenadine, tolbutamide and zolpidem: increase in their plasmatic concentrations with possible potentialization of their toxicity, by the inhibition of their hepatic metabolism due to KETOCONAZOLE.

Route of administration: Topical.

Presentation: Topical cream in a 30g tube.

Storage conditions:

Keep in a cool and dry place (below 30°C), protect from light.
Keep out of reach of children.

PS PHARMACEUTICAL, S.A.

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