Ketocon® Cream

Ketoconazole

Description
Ketoconazole (**Ketocon®**) is a synthetic imidazole dioxolane derivative, has a potent antifungal activity against dermatophytes, such as *Trichophyton sp., Epidermophyton spp., Microsporum spp.,* and *yeasts,* such as *Candida spp.* and *Malassezia spp. (Pityrosporum sp.).*

Composition
Ketocon® 2% Cream: Each gram contains Ketoconazole BP 20 mg.

Indications
Ketocon® 2% cream is used for topical application in the treatment of dermatophyte infections of the skin such as tinea corporis, tinea cruris, tinea pedis (athlete's foot) infections due to *Trichophyton spp., Microsporon spp.* and *Epidermophyton spp.* **Ketocon®** 2% cream is also indicated for the treatment of cutaneous candidiasis (including vulvitis), candidal intertrigo (sweat rash), tinea (pityriasis) versicolor and seborrhoeic dermatitis caused by *Malassezia* (previously called *Pityrosporum spp.*).

Dosage & administration
Tinea Versicolor: Apply to the affected and immediate surrounding area once a day for 2 weeks.
Cutaneous Candidiasis: Apply to the affected and immediate surrounding area once a day for 2 weeks.
Tinea Corporis: Apply to the affected and immediate surrounding area once a day for 2 weeks.
Tinea Cruris: Apply to the affected and immediate surrounding area once a day for 2 weeks.
Tinea Pedis: Apply to the affected and immediate surrounding area once a day for 6 weeks.
Seborrheic Dermatitis: Apply to affected area twice a day for 4 weeks or until clinical clearing.

Contraindications
Known hypersensitivity to Ketoconazole or any of the excipients.

Side effects
Commonly observed adverse reactions to Ketoconazole cream in clinical trials were skin application site burning sensation, erythema and pruritus. Uncommon adverse reactions are application site bleeding, discomfort, dryness, inflammation, irritation, paraesthesia and reaction; bullous eruption, dermatitis contact, rash, skin exfoliation and sticky skin.

Use in pregnancy & lactation
There are no adequate and well-controlled studies in pregnant or lactating women. To date, no other relevant epidemiological data are available. Data on a limited number of exposed pregnancies indicate no adverse effects of topical Ketoconazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity following oral administration of Ketoconazole. No effects on the breastfed newborn/infant are anticipated.

Precautions
Not for ophthalmic use. If a potent topical corticosteroid has been used previously in the treatment of seborrheic dermatitis, a recovery period of 2 weeks should be allowed before using Ketoconazole 2% w/w cream, as an increased incidence of steroid induced skin sensitization has been reported when no recovery period is allowed.

Drug interactions
Not known.

Over dosage
Exaggerated topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment. If accidental ingestion of Ketoconazole 2% w/w cream occurs, no special measures have to be taken.

Storage
Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging
Ketocon® 2% Cream: Each carton contains a lami tube having 30 gm cream.

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