

NIZORAL*

ketoconazole 2% Cream

Presentation

NIZORAL Cream contains the synthetic broad-spectrum anti-fungal agent, ketoconazole. Each gram contains 20mg ketoconazole. The cream formulation consists of propylene glycol, stearyl alcohol, cetyl alcohol, sorbitan stearate, polysorbate, isopropyl myristate, sodium sulphite and purified water

Uses

Actions

Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antimycotic activity against dermatophytes such as *Trichophyton sp.*, *Epidermophyton floccosum* and *Microsporum sp.* and against yeasts. In particular the effect on *Pityrosporum sp.* is very pronounced.

Usually ketoconazole cream acts very rapidly on pruritus which is commonly seen in dermatophyte and yeast infections as well as skin conditions associated with the presence of *Pityrosporum sp.* This symptomatic improvement is observed before the first signs of healing are observed.

Pharmacokinetics

NIZORAL Cream does not produce detectable blood levels after topical application.

Indications

NIZORAL Cream is indicated for topical application in the treatment of dermatophyte infections of the skin; tinea corporis, tinea cruris, tinea manus and tinea pedis due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Microsporum canis* and *Epidermophyton floccosum*, as well as in the treatment of cutaneous candidiasis and tinea (pityriasis) versicolor. NIZORAL Cream is also indicated for the treatment of seborrhoeic dermatitis, a skin condition associated with the presence of *Pityrosporum ovale*.

Dosage and Administration

Cutaneous candidiasis, tinea corporis, tinea cruris, tinea manus, tinea pedis and tinea (pityriasis) versicolor: it is recommended that NIZORAL 2% Cream be applied once daily to cover the affected and immediate surrounding area.

Seborrhoeic dermatitis: NIZORAL 2% Cream should be applied to the affected area once or twice daily depending on the severity of infection.

Treatment should be continued for a sufficient period, at least until a few days after disappearance of all symptoms. The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks of treatment. General measures in regard to hygiene should be observed to control sources of infection or reinfection.

The usual duration of treatment is: tinea versicolor 2-3 weeks, yeast infections 2-3 weeks, tinea cruris 2-4 weeks, tinea corporis 3-4 weeks, tinea pedis 4-6 weeks. The usual duration of treatment in seborrhoeic dermatitis is 2 to 4 weeks. Maintenance therapy is applied once or twice weekly in seborrhoeic dermatitis.

Contraindications

NIZORAL Cream is contraindicated in individuals who have shown hypersensitivity to any of its ingredients.

Warnings and Precautions

NIZORAL Cream is not for ophthalmic use. For external use only. To prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids it is recommended to continue applying a mild topical corticosteroid in the morning and to apply NIZORAL Cream in the evening and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks.

Use in Pregnancy and Lactation

NIZORAL Cream applied topically is not absorbed, so it can be used during pregnancy and lactation.

Interactions

Not applicable, since NIZORAL Cream is not absorbed to any measurable extent.

Adverse Effects

A few instances of irritation and burning sensation have been observed during treatment with NIZORAL Cream. Also in rare circumstances allergic local skin phenomena, such as contact dermatitis, have been associated with NIZORAL Cream or one of its components, namely sodium sulphite or propylene glycol.

Overdosage

Excessive topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment. No special measures have to be taken in case of accidental ingestion.

Medicine Classification

Pharmacy Only Medicine

Package Quantities

NIZORAL Cream is supplied in tubes of 15g and 30g

Pharmaceutical Precautions

Store at room temperature. Keep out of reach of children.

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