KAZOL CREAM
Ketoconazole Cream 2 % w/w

Composition:

Ketoconazole	BP	2 % w/w
Cream Base		q.s.
Preservatives:		
Methylparaben	BP	0.18 % w/w
Propylparaben	BP	0.02 % w/w

PHARMACODYNAMICS:
Pharmacotherapeutic group: Antifungals for Topical Use, Imidazole and triazole derivatives

ATC Code: D01AC08

Usually Ketoconazole cream acts rapidly on pruritus, which is commonly seen in dermatophyte and yeast infections, as well as skin conditions associated with the presence of Malassezia spp. This symptomatic improvement is observed before the first signs of healing are observed.

Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antimycotic activity against dermatophytes such as Trichophyton spp., Epidermophyton floccosum and Microsporum spp. and against yeasts, including Malassezia spp. and Candida spp. The effect on Malassezia spp. is particularly pronounced.

PHARMACOKINETICS:
Plasma concentrations of ketoconazole were not detectable after topical administration of KAZOL Cream in adults on the skin. In one study in infants with seborrhoeic dermatitis (n = 19), where approximately 40 g of KAZOL cream was applied daily on 40% of the body surface area, plasma levels of ketoconazole were detected in 5 infants, ranging from 32 to 133 ng/mL.

INDICATIONS:
Ketoconazole is used to treat skin infections such as athlete's foot, jock itch, ringworm. This medication is also used to treat a skin condition known as pityriasis (tinea versicolor), a fungal infection that causes a lightening or darkening of the skin of the neck, chest, arms, or legs.

POSOLOGY AND METHOD OF ADMINISTRATION:
Use this medication on the skin only. Clean and thoroughly dry the area to be treated. Apply this medication to the affected skin, usually once or twice a day or as directed by your doctor. Dosage and length of treatment depends on the type of infection being treated. Do not apply this more often than prescribed. Your condition will not clear faster, but side effects may be increased.

Apply enough medication to cover the affected skin and some of the surrounding skin. After applying this medication, wash your hands. Do not wrap, cover or bandage the area unless directed to do so by your doctor.

Do not apply this medication in the eyes, nose, mouth, or vagina. If this medication gets in the eyes (e.g., when used to treat dandruff), rinse thoroughly with water.

Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time(s) each day.

Continue to use this medication until the full prescribed amount is finished, even if symptoms disappear after starting ketoconazole. Stopping the medication too early may allow the fungus to continue to grow, which may result in a relapse of the infection.

Inform your doctor if your condition persists after the prescribed amount of treatment or worsens at any time.

PRECAUTIONS AND WARNINGS:
KAZOL cream is not for ophthalmic use.

If co-administered with a topical corticosteroid, 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 KAZOL cream in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2-3 weeks.

CONTRAINDICATIONS:
KAZOL cream is contra-indicated in patients with a known hypersensitivity to any of the ingredients or to ketoconazole itself.

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:
No interaction studies have been performed

PREGNACY AND LACTATION:
There are no adequate and well-controlled studies in pregnant or lactating women. 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 at doses that are not relevant to the topical administration of ketoconazole.

Plasma concentrations of ketoconazole are not detectable after topical application of KAZOL Cream to the skin of non-pregnant humans. There are no known risks associated with the use of KAZOL Cream in pregnancy or lactation.

ADVERSE REACTIONS:
Stinging, swelling, irritation, or redness of the treated skin may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
KAZOL cream has no influence on the ability to drive and use machines.

OVERDOSE:

Topical Application

Excessive topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment.

Ingestion

In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

INCOMPATIBILITY:
Not applicable.

SHELF LIFE:
24 Months

PACKAGING:
30 gm tube packed in a carton along with pack insert.

STORAGE CONDITION:
Store in a cool, dry place below 30°C. Protect from light.
Keep out of reach of children.

DISTRIBUTED BY:
Relief Pharma Ltd.
5th Street of Taimany, Kabul
Afghanistan.

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CIAN HEALTHCARE PVT. LTD.
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