

Applezoral
Cream

Ketoconazole Cream BP 2%w/w

30 g

Applezoral
Cream

NAFDAC Reg No:

Composition:
Ketoconazole BP 2%w/w
Cream base q.s.

FOR EXTERNAL USE ONLY

Direction for Use : As indicated by your doctor or see the package leaflet.
Storage : Store in a cool, dark place.
To be used only under Medical Supervision.
Keep the medicine out of reach of children.

Ketoconazole Cream BP 2%w/w

30 g

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NAFDAC Reg No:



Marketed by:
Suitelife Pharmaceutical Ltd.
4, Ayo Davies Close,
Off Ekolou Street, Surulere,
Lagos, Nigeria

Manufactured in India by:
SYSTOCHEM LABORATORIES LTD.
B-75, Roop Nagar Indl. Area
Loni Ghaziabad (U.P.) 201102
A WHO-GMP Certified Company

Mfg. Lic. No. : **17/SC/P/96**

Batch No.

Mfg. Date

Exp. Date

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Applezoral
Cream

APPLEZORAL CREAM

(Ketoconazole Cream BP 2% w/w.)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

GENERIC NAME: - Ketoconazole Cream BP 2% w/w

BRAND NAME - APPLEZORAL CREAM

2. Qualitative and quantitative composition

Composition

Ketoconazole BP 2.0% w/w

Cream Base q.s

3. Pharmaceutical form

Cream

A smooth white cream.

4. Clinical particulars

4.1 Therapeutic indications

For the treatment of:

Ketoconazole is used to treat skin infections such as athlete's foot, jock itch, ringworm, and certain kinds of dandruff. 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.

4.2 Posology and method of administration

Posology

There is no separate dosage schedule for the young or elderly.

Method of administration

The cream should be applied thinly and evenly to the affected area 2 – 3 times daily and rubbed in gently. A strip of cream (½ cm long) is enough to treat an area of about the size of the hand.

If the feet are infected, they should be thoroughly washed and dried, especially between the toes, before applying the cream.

It should not be ingested or used intravaginally. The eyes and mucous membranes should also be avoided. Patients should apply the cream and gel only to the affected area and the areas immediately surrounding it.

4.3 Contraindications

Ketoconazole Cream 2% is contraindicated in persons who have shown hypersensitivity to the active or excipient ingredients of this formulation.

4.4 Special warnings and precautions for use

Before using ketoconazole, tell your doctor or pharmacist if you are allergic to it; or to otherazole antifungals such as clotrimazole, econazole, or miconazole; or if you have any other allergies. this product may contain inactive ingredients, which can cause allergic reactions or other problems. talk to your pharmacist for more details.before using this medication, tell your doctor or pharmacist your medical history.this medication should be used only if clearly needed during pregnancy. discuss the risks and benefits with your doctor.it is unknown if this drug passes into breast milk. Consult your doctor before breast-feeding.

4.5 Interaction with other medicinal products and other forms of interaction

Ketoconazole must not be used with certain other medications because a serious, possibly fatal, drug interaction may occur. Ketoconazole interacts with drugs such as disopyramide, dofetilide, dronedarone, methadone, pimozide, quinidine, ranolazine, among others.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Animal studies revealed evidence of embryotoxicity and teratogenicity. There are no controlled data in human pregnancy. AU TGA pregnancy category B3: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have shown evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.

Lactation:

there is little published experience with ketoconazole or levoketoconazole during breastfeeding and its potential liver enzyme inhibition and liver toxicity, other agents are preferred. The manufacturers recommend that mothers taking ketoconazole or levoketoconazole avoid breastfeeding during treatment and for 1 day after the last dose..

Fertility:

A sharp decline in fertility (50% negative) in Ketoconazole treated mice was observed. A significant reduction in the total protein and sialic acid contents of testes, epididymis, seminal vesicle and ventral prostate were noticed.

4.7 Effects on ability to drive and use machines

Ketoconazole Cream has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

As the listed undesirable effects are based on spontaneous reports, assigning an accurate frequency of occurrence for each is not possible. Acne, bleeding from sore in the mouth, blistering, crusting, irritation, itching, or reddening of the skin, burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings, cracked, dry, or scaly skin, discoloration of the fingernails or toenails, dizziness, eye dryness, irritation, or swelling, red rash with watery, yellow-colored, or pus filled blisters with or without thick yellow to honey-colored crusts, skin dryness, pain, rash, redness, or swelling sore in the mouth or on the gums, swelling of the face.

Reporting of suspected adverse reactions

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects.

4.9 Overdose

Ketoconazole has rarely caused very serious (possibly fatal) liver problems. Get medical help right away if you develop symptoms of liver problems, including nausea/vomiting that doesn't stop, stomach/abdominal pain, dark urine, yellowing eyes/skin, loss of appetite, or light colored stools. However, in the event of accidental oral ingestion, routine measures such as gastric lavage.

5. Pharmacological properties

5.1 Pharmacodynamic properties **Mechanism of Action**

Ketoconazole interacts with 14- α -sterol demethylase, a cytochrome P-450 enzyme necessary for the conversion of lanosterol to ergosterol.⁵ This results in inhibition of ergosterol synthesis and increased fungal cellular permeability due to reduced amounts of ergosterol present in the fungal cell membrane. This metabolic inhibition also results in accumulation of 14 α -methyl-3,6-diol, a toxic metabolite. The increase in membrane fluidity is also thought to produce impairment of membrane-bound enzyme systems as components become less closely packed

Pharmacodynamic Effects

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5.2 Pharmacokinetic properties

Ketoconazole requires an acidic environment for dissolution and systemic absorption. It does not enter the central nervous system. Ketoconazole is a potent inhibitor of hepatic P450 enzymes; thus dosage adjustments may be necessary to prevent adverse drug interactions..

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Ketoconazole Cream was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats Ketoconazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. Pharmaceutical particulars

6.1 List of excipients

Cetostearyl Alcohol, CM 1000, Propyl Glycol Plain, LLP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool dark place .

6.5 Nature and contents of container

Lami tube with cap.

Pack sizes: 30GM

6.6 Special precautions for disposal and other handling

No special requirements

7.0 EXPORTER

TRIOPLUS PHARMACEUTICALS PVT. LTD.
106, Samruddhi commercial complex, Mindspace,
Malad (west), Mumbai – 400064
+91 9833905895
+91 22 49705095

8.0 MANUFACTURER

SYSTOCHEM LABORATORIES LTD.,
B-75, Roop Nagar Industrial Area, Loni,
Ghaziabad (UP)- 201102

9.0 MARKETING AUTHORITY

SUITELIFE PHARMACEUTICAL LTD.
4, Ayo Davies Close, Off Ekolou Street,
Surulere, Lagos, Nigeria..