

LUZO

Luliconazole Cream 1% w/w

Composition:

Luliconazole 1 % w/w
Cream Base q.s.

PHARMACODYNAMICS:

Pharmacotherapeutic group: Antifungals for Topical Use.

Mechanism of action:

Luliconazole is an antifungal that belongs to the azole class. Although the exact mechanism of action against dermatophytes is unknown, luliconazole appears to inhibit ergosterol synthesis by inhibiting the enzyme lanosterol demethylase. Inhibition of this enzyme's activity by azoles results in decreased amounts of ergosterol, a constituent of fungal cell membranes, and a corresponding accumulation of lanosterol.

PHARMACOKINETICS:

Luliconazole is the R enantiomer of a chiral molecule. The potential for inter-conversion between R and S enantiomers in humans has not been assessed. Information on the pharmacokinetics of luliconazole presented below refers to both R enantiomer and S enantiomer, if any, combined. Luliconazole is >99% protein bound in plasma.

INDICATION:

Luliconazole Cream, 1% is indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*, in patients 18 years of age and older.

POSOLOGY AND METHOD OF ADMINISTRATION:

For topical use only. Luliconazole is not for ophthalmic, oral, or intravaginal use. When treating tinea pedis, a thin layer of Luliconazole should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily for 2 weeks. When treating tinea cruris or tinea corporis, Luliconazole should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily for 1 week.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Luliconazole is for external use only, avoid contact with eyes. Do not apply to the cornea and conjunctiva as ophthalmic use. Do not apply to the areas with marked erosion/fissures.

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:

The potential of luliconazole to inhibit cytochrome P-450 (CYP) enzymes 1A2, 2C9, 2C19, 2D6, and 3A4 was evaluated in vitro. Based on in vitro assessment, luliconazole at therapeutic doses, particularly when applied to patients with moderate to severe tinea cruris, may inhibit the activity of CYP2C19 and CYP3A4. However, no in vivo drug interaction trials have been conducted to evaluate the effect of luliconazole on other drugs that are substrates of CYP2C19 and CYP3A4. Luliconazole is not expected to inhibit CYPs 1A2, 2C9 and 2D6 based on in vitro assessment. The induction

potential of luliconazole on CYP enzymes has not been evaluated.

CONTRAINDICATION:

Hypersensitivity to the active substance or to any of the excipients.

PREGNANCY & LACTATION:

Pregnancy Category C

There are no adequate and well-controlled studies of Luliconazole 1%, in pregnant women. It should be used during pregnancy only if potential benefit justifies the potential risk to the foetus.

Lactation

It is not known whether Luliconazole is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Luliconazole 1% is pre-scribed to women who are breastfeeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

There are no any effects shown after using this cream

SIDE EFFECTS:

Common:

- ÿ Itching
- ÿ Skin irritation or redness
- ÿ Contact dermatitis
- ÿ Eczema

OVERDOSE:

There are no any effects shown after using this cream.

INCOMPATIBILITY:

None

SHELF LIFE:

36 Months

PACKAGING:

10 gm laminated tube with tray is packed in a printed carton along with pack insert.

STORAGE CONDITION:

Store in cool & dry place, below 30°C. Protect from light & moisture.

Do not freeze. Avoid contact with eyes.

Keep the tube tightly closed after use.

Keep out of reach of children.

Product of



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