



1.17. Summary Product Characteristics (SPC)

1.17.1 Product Information for Health Professional

1. Name of the medicinal product

Luliconazole Cream.

1.1 Strength:

Luliconazole.....1.00%w/w
Preservative:
Benzyl Alcohol BP.....1.00%w/w

2. Qualitative and Quantitative composition

Luliconazole.....1.00%w/w
Preservative:
Benzyl Alcohol BP.....1.00%w/w
Cream Base.....q.s.

3. Pharmaceutical form

Semi-Solid Dosage Form (Cream)

4. Clinical particulars

4.1 Therapeutic indications;

TINEAHIT (Luliconazole Cream) is an azole antifungal 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..

Mechanism of Action:

TINEAHIT (Luliconazole Cream) 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.

4.2 Posology and method of administration

For topical use only. TINEAHIT (Luliconazole Cream) is not for ophthalmic, oral or intravaginal use. When treating interdigital Tinea Pedis, a thin layer of TINEAHIT(Luliconazole Cream) should be applied to the affected area and approximately 1 inch surrounding area(s) once daily for two weeks. When treating Tinea Cruris and Tinea Corporis, TINEAHIT (Luliconazole Cream) should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily for one week. For external use only.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use



Inform patients that TINEAHIT (Luliconazole Cream) is for topical use only. TINEAHIT (Luliconazole Cream) is not intended for intravaginal or ophthalmic use.

4.5 Interaction with other medicinal products and other forms of interaction

The potential of luliconazole cream to inhibit cytochrome P-450 (CYP) enzymes 1A2, 2C9, 2C19, 2D6, and 3A4 was evaluated in vitro. Based on in vitro assessment, luliconazole cream 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 cream on other drugs that are substrates of CYP2C19 and CYP3A4. Luliconazole Cream is not expected to inhibit CYPs 1A2, 2C9 and 2D6 based on in vitro assessment. The induction potential of luliconazole cream on CYP enzymes has not been evaluated.

4.6 Fertility, pregnancy and lactation

Pregnancy

Category C, There are no adequate and well-controlled studies of luliconazole cream in pregnant women.

Luliconazole cream should be used during pregnancy only if the potential benefit justifies the potential risk to the unborn baby.

Lactation

It is not known if luliconazole cream crosses into human milk. Because many medications can cross into human milk and because of the possibility for serious adverse reactions in nursing infants with use of this medication, a choice should be made whether to stop nursing or stop the use of this medication. Your doctor and you will decide if the benefits outweigh the risk of using luliconazole cream.

4.7 Effects on ability to drive and use machines

TINEAHIT (Luliconazole Cream) does not usually affect your ability to drive.

4.8 Undesirable effects

Skin irritation may occur. If it persists or worsens, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

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. If you notice other effects not listed above, contact your doctor or pharmacist.

4.9 Overdose

If you use too much luliconazole cream, call your healthcare provider or local Poison Control Center, or seek emergency medical attention right away.



5. Pharmacological properties

5.1 Pharmacodynamic properties

Luliconazole

At therapeutic doses, TINEAHIT (Luliconazole Cream) is not expected to prolong QTc to any clinically relevant extent.

5.2 Pharmacokinetic properties

Luliconazole

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. In a pharmacokinetic trial, 12 subjects with moderate to severe tinea pedis and 8 subjects with moderate to severe tinea cruris applied a mean daily amount of approximately 3.5 grams of Luliconazole Cream, 1% to the affected and surrounding areas once daily for 15 days. Plasma concentrations of luliconazole on Day 15 were measurable in all subjects and fluctuated little during the 24 hour interval. In subjects with tinea pedis, the mean \pm SD of the maximum concentration (C_{max}) was 0.40 ± 0.76 ng/mL after the first dose and 0.93 ± 1.23 ng/mL after the final dose. The mean time to reach C_{max} (T_{max}) was 16.9 ± 9.39 hours after the first dose and 5.8 ± 7.61 hours after the final dose. Exposure to luliconazole, as expressed by area under the concentration time curve (AUC₀₋₂₄) was 6.88 ± 14.50 ng*hr/mL after the first dose and 18.74 ± 27.05 ng*hr/mL after the final dose. In subjects with tinea cruris, the mean \pm SD C_{max} was 4.91 ± 2.51 ng/mL after the first dose and 7.36 ± 2.66 ng/mL after the final dose. The mean T_{max} was 21.0 ± 5.55 hours after the first dose and 6.5 ± 8.25 hours after the final dose. Exposure to luliconazole, as expressed by AUC₀₋₂₄ was 85.1 ± 43.69 ng*hr/mL after the first dose and 121.74 ± 53.36 ng*hr/mL after the final dose.

5.3 Preclinical safety data

Long-term studies to evaluate the carcinogenic potential of Luliconazole Cream, 1% have not been conducted. Luliconazole revealed no evidence of mutagenic or clastogenic potential based on the results of two in vitro genotoxicity tests (Ames assay and Chinese hamster lung cell chromosomal aberration assay) and one in vivo genotoxicity test (mouse bone marrow micronucleus test). In a fertility study in rats, subcutaneous doses of 1, 5 and 25 mg/kg/day luliconazole were administered prior to and during mating and through early pregnancy.

Treatment related effects on reproductive function were noted in females (decreased live embryos and decreased corpus luteum) at 5 and 25 mg/kg/day and males (decreased sperm counts) at 25 mg/kg/day. No treatment related effects on fertility or reproductive function were noted at 1 mg/kg/day (0.1X MRHD based on BSA comparisons).



CURETECH SKINCARE
Plot No. 33 & 34, Phase – IV, Bhatoli
Kalan, Baddi, Distt. Solan (HP)

MODULE -1
TINEAHIT
(LULICONAZOLE CREAM)

6. Pharmaceutical particulars:

6.1 List of Excipients

Benzyl alcohol
Butylated Hydroxy Toluene
Cetostearyl Alcohol
Isopropyl Myristate
Caprylic and Capric Triglycerides
Methyl Paraben
Polysorbate 60
Propylene Glycol
Sorbitan Monostearate
Rose Musk
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30⁰ C. protect from light.
Do not freeze.

6.5 Nature and contents of container

The cream is filled in printed laminated tubes with internal lacquer coating and HDPE screw-on caps and enclosed in an outer carton along with pack insert. Pack sizes available are 20g.

6.6 Special precautions for disposal and other handling

No Special requirements.

7. Marketing authorisation holder

Not Applicable

8. Marketing authorisation number(s)

Not Applicable

9. Date of first authorisation/renewal of the authorization

Not Applicable

10. Date of revision of the text

Not Applicable