Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

Luliconazole Cream 1%w/w

2. Qualitative and Quantitative Composition

Qualitative declaration

Luliconazole
Excipient(s) with known effect: Propylene glycol, Benzyl alcohol and Butylated hydroxytoluene

Quantitative declaration

For full list of Excipients, see section 6.1.

3. Pharmaceutical Form

Topical Cream
Off white to pale yellow color smooth cream.
Distribution Category: POM.

4. Clinical Particulars

4.1.1. Indications

Luliconazole Cream 1% w/w is a topically indicated to treatment of fungal infections in people with interdigital tinea pedis (athlete's foot that is between the toes), tinea cruris (jock itch or ringworm) and tinea corporal (ringworm of body) caused by the organisms.

4.2. Posology and Method of Administration

Method of administration: For Topical Use Only, Not for Ophthalmic, oral, or Intravaginal use.
For the treatment of interdigital tinea pedis (athlete's foot that is between the toes)
Adults: Apply a thin layer of cream topically to affected areas, and approximately 1 inch of the immediate surrounding areas, once daily for 2 weeks.
Children and Adolescents 12 to 17 years: Apply a thin layer of cream topically to affected areas, and approximately 1 inch of the immediate surrounding areas, once daily for 2 weeks.
For the treatment of tinea cruris (jock itch or ringworm) and tinea corporis (Ringworm of body):
Adults: Apply topically to affected areas, and approximately 1 inch of the immediate surrounding areas, once daily for 1 week.
Children and Adolescents 12 to 17 years: Apply topically to affected areas, and approximately 1 inch of the immediate surrounding areas, once daily for 1 week.

4.3. Contraindications

Luliconazole Cream 1% w/w has not known contraindications.

4.4. Special Warnings and Special Precautions for Use

It is for external use only. Do not let cream get into your eyes, nose, or mouth, other mucous membranes and do not swallow it.

Avoid ocular exposure to luliconazole; do not administer by ophthalmic administration. If ocular exposure occurs, treat by immediately flushing the affected eye with cool, clean water.
Wash hands before and after application. Use exactly as stated dose by physician.

Use in Specific Populations:

Pediatric Use: Appropriate studies have not been performed on the relationship of age to the effects of luliconazole topical cream in children younger than 12 years of age to treat tinea pedis and tinea cruris and in children younger than 2 years of age to treat tinea corporis. Safety and efficacy have not been established.

Geriatric Use: Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of luliconazole topical cream in the elderly. However, elderly patients are more sensitive to the effects of this medicine than younger adults.

Children:
Age 2 to 12 years: Specific dosage information is not available.
Younger than 2 years: Safety and efficacy have not been established.

Hepatic Impairment: No dosage adjustment is required.

Renal Impairment: No dosage adjustment is required.

It contain excipients known effect:
Propylene glycol: Propylene glycol may cause skin irritation. Do not use this medicine in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns) without talking to your doctor or pharmacist. Benzyl alcohol: Benzyl alcohol may cause mild local irritation.
Butylated hydroxytoluene: May cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

4.5. Interaction with other medicinal products and other forms of interaction

Not known.

4.6. Fertility, Pregnancy and Lactation

Pregnancy: No adequate and controlled studies have been conducted to evaluate use of Luliconazole Cream 1%w/w in pregnant women; administer during pregnancy only if the potential benefits to the mother justify the possible risks to the fetus.
Lactation: It is not known if it is excreted in human milk, caution is advised when administering to lactating women.

4.7. Effects on ability To Drive and use Machines

No Known

4.8. Undesirable Effects

It may cause moderate skin reactions at the treatment site, contact dermatitis, mild: skin irritation may happen.

4.9. Overdose

Overdose treatment should be supportive or symptomatic.

5. Pharmacological Properties

1. Pharmacodynamics Properties

Pharmacotherapeutic Group: Topical Anti-Fungal
ATC Code: D01AC18
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.
Mechanism of Resistance: Luliconazole cream 1%w/w has been shown to be active against most isolates of the fungi, both Trichophyton rubrum, Epidermophyton floccosum.

2. Pharmacokinetic Properties

After administered topically systemic absorption, the drug is more than 99% bound to plasma proteins. Distribution, metabolism, and excretion are not known. It may affected cytochrome P450 isoenzymes CYP2C19, CYP3A4, CYP2C8, and CYP2B6.

3. Preclinical Safety Data

Not Known

6. Pharmaceutical Particulars

6.1. List of Excipients

Propylene Glycol BP
Medium Chain Triglycerides BP
Isopropyl Myristate BP
Sepinco P 600 (Acrylamide / Sodium Acryloyldimethyl Tau rate Copolymer /sohexadecane / Polysorbate 80) IHS
Benzyl Alcohol BP
Butylated Hydroxytoluene BP
Purified water BP

6.2. Incompatibilities

Not applicable.

6.3. Shelf Life

24 months
Use the cream within 28 days after opening the container..

6.4. Special Precautions for Storage

Do not store above 30°C. Protect from light. Do note freeze.

6.5. Nature and Contents of Container

30gm Cream packed in printed laminated tube. Such 1 tube packed in printed carton with package insert.

6.6. Special precaution for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder And Manufacturing Site Addresses

Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal. Kalol,
Dist. Gandhinagar,
Gujarat, India.
Phone: +91-02764-665000, 305000
Telefax: +91-02764-281809
Email: khatraj@lincolnpharma.com

Website: www.lincolnpharma.com

Name and Address of manufacturing site(s)
Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Tal. Kalol,
Dist. Gandhinagar,
Gujarat, India.
Phone: +91-02764-665000, 305000
Telefax: +91-02764-281809
Email: khatraj@lincolnpharma.com
Website: www.lincolnpharma.com

8. Marketing Authorization Number

TAN 22 HM 246

9. Date of First <Registration> / Renewal of The <Registration>

19th July, 2022

10. **Date of Revision of the Text**