SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Lulileb Cream**
1.2 Generic Name : **Luliconazole Cream 1%w/w**
1.3 Strength : **Luliconazole 1%w/w**
1.4 Pharmaceutical Form : **Cream**

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Luliconazole		1 % w/w
Methyl Paraben	BP	0.14 % w/w
Benzyl Alcohol	BP	1 % w/w
Cream base		q.s.

3. PHARMACEUTICAL FORM

Cream

White coloured, perfumed Smooth Cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Lulileb Cream is indicated for the topical treatment of Athlete's Foot (Tinea Pedis), Jock Itch (Tinea Cruris), and Ringworm (Tinea Corporis, Trichophyton Rubrum, Microsporum Gypseum & Epidermophyton Floccosum).

4.2 Posology and method of administration

A thin layer of Luliconazole Cream, 1% should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily for 1 to 2 weeks.

Athlete's Foot (Tinea Pedis) : Once daily for 2 weeks, or as directed by the Physician.
Jock itch & Ringworm (Tinea Cruris or Tinea Corporis) : Once daily for 1 weeks.

4.3 Contraindications

Luliconazole is an azole antifungal; avoid use in patients with a history of azole antifungal hypersensitivity.

4.4 Special warnings and special precautions for use

Lulileb Cream is For External Use Only. Do not use Luliconazole Cream near to eyes, mouth or vagina.

4.5 Interaction with other FPPs and Other forms of Interaction

An in vivo study in adult subjects with moderate to severe tinea pedis and tinea cruris showed that Luliconazole Cream, 1% is mostly a weak inhibitor of CYP2C19.

4.6 Pregnancy and lactation

Pregnancy: There are no available data with Luliconazole Cream, 1% use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. In animal reproduction studies with pregnant rats and rabbits, there were no adverse developmental effects observed with subcutaneous administration of Luliconazole during organogenesis at doses up to 3 and 24 times. Luliconzole Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: There is no information available for the presence of Luliconazole in human milk, the effects of the drug on the breast fed infant, or the effects of the drug on milk production after topical application of Luliconazole Cream 1% to women who are breast feeding. Caution should be exercised when Luliconazole Cream is applied to breast feeding women.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Luliconazole may show mild skin irritation.

4.9 Overdose & Treatment

An accidental overdose of Luliconazole Cream, symptomatic treatment should be provided as prescribed by the Physician.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Antifungal.

Luliconazole is thought to inhibit the enzyme lanosterol demethylase.

Lanosterol demethylase is needed for the synthesis of ergosterol, which is a major component of the fungus cell membranes. Luliconazole has been shown to be active against most isolates of the following fungi like Trichophyton Rubrum & Epidermophyton floccosum.

5.2 Pharmacokinetic properties

Although Luliconazole is applied topically, clinical studies have shown that after the first dose in patients with Tinea Pedis, a maximum plasma concentration of 0.40 ± 0.76 ng/mL (mean ± SD) occurred in 16.9 ± 9.39 hours (mean ± SD). Plasma protein binding of Luliconazole is >99%.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

SN	Ingredients	Spec.
01.	Luliconazole	IH
02.	Benzyl Alcohol	BP
03.	Methyl Paraben	BP
04.	Butylated Hydroxytolune	BP
05.	Cetostearyl Alcohol	BP
06.	Isopropyl Myristate	BP
07.	Sorbitan Monostearate	BP
08.	Polysorbate-60	BP
09.	Propylene Glycol	BP
10.	Medium Chain Triglyceride	BP
11.	Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 month from the date of manufacturing.

6.4 Special precautions for storage

Do not Freeze. Store at a temperature not exceeding 30°C. Protect from light. Keep Out of reach of Children.

6.5 Nature and contents of container

15 gm in an Aluminium barrier Laminate tube in an inner carton.

30 gm in an Aluminium barrier Laminate tube in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

07966/08976/NMR/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Oct 21, 2022

10 DATE OF REVISION OF THE TEXT

01/01/2023