SUMMARY PRODUCT CHARACTERISTICS (SPC):

(PRODUCT DATA SHEET)

1. Name of the Medicinal Product:

1.1 Product Name:

LULICOR CREAM (Luliconazole Cream 1 % w/w)

1.2 Strength:

Luliconazole 1% w/w

Benzyl alcohol BP (Preservative) 1 % w/w

Cream base..... q.s.

1.3 Pharmaceutical Dosage Form:

Cream For Topical use.

2. Quality and Quantitative Composition

Luliconazole 1% w/w

Benzyl Alcohol BP 1%w/w (Preservative)

Cream Base q.s

2.1 Qualitative Declaration

For Excipients see section 6.1

2.2 Quantitative Declaration:

Luliconazole 1% w/w

Benzyl Alcohol BP 1%w/w (Preservative)

Cream Base q.s

For Excipients see section 6.1

3. Pharmaceutical Form:

Cream for Topical use.
A White colour smooth cream.

4. Clinical Particulars

4.1 Therapeutic indications:

LULICOR CREAM (Luliconazole Cream 1 % w/w) is indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms Trichophyton rubrum and Epidermophyton floccosum.

PRODUCT: LULICOR CREAM (Luliconazole Cream 1% w/w)

COUNTRY: KENYA

4.2 Posology and method of administration:

Posology:

For topical use only. Luliconazole Cream 1 % w/w is not for ophthalmic, oral, or intravaginal use.

- When treating interdigital tinea pedis, a thin layer of Luliconazole Cream 1 % w/w 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 Cream 1 % w/w should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily for 1 week.

4.3 Contraindications

Luliconazole is contraindicated in patients who have demonstrated hypersensitivity to Luliconazole or any other inactive ingredients in the formulation.

4.4 Special warning and precautions for use:

Luliconazole Cream 1 % w/w 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.

4.5 Interaction with other medicinal products and other forms of Interactions

Results of in vitro studies indicated that therapeutic doses of Luliconazole Cream 1% w/w did not inhibit cytochrome P450 (CYP) enzymes 1A2, 2C9 and 2D6, but can inhibit the activity of CYP2B6, 2C8, 2C19 and 3A4. The most sensitive enzyme, CYP2C19, was further evaluated in an in vivo study using omeprazole as a probe substrate in adult subjects with moderate to severe interdigital tinea pedis and tinea cruris. The result showed that Luliconazole cream 1% w/w applied at a daily amount of approximately 4 grams increased the omeprazole systemic exposure (AUC) by approximately 30 % compared to the exposure of the omeprazole administered alone. Luliconazole cream 1 % w/w is considered a weak inhibitor of CYP2C19. For tinea cruris, extrapolation from both in vitro inhibition studies and in vivo data in adults to the adolescent subjects showed that in some subjects, levels of luliconazole can approach or exceed those required to be a moderate inhibitor of CYP2C19.

Results of in vitro studies indicated that therapeutic doses of Luliconazole cream 1% w/w did not induce CYP1A2, 2B6 and 3A4.

4.6 Fertility, Pregnancy and lactation:

Pregnancy

Risk Summary

There are no available data with Luliconazole Cream 1 % w/w 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, respectively, the maximum recommended human dose (MRHD).

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

The animal multiples of human exposure calculations were based on daily dose body surface area (BSA) comparisons (mg/m2) for the reproductive toxicology studies described in this section and in Section 13.1. The maximum recommended human dose (MRHD) was set at 8 g 1% cream per day (1.33 mg/kg/day for a 60 kg individual, which is equivalent to 49.2 mg/m2/day).

Systemic embryofetal development studies were conducted in rats and rabbits. Subcutaneous doses of 1, 5 and 25 mg/kg/day luliconazole were administered during the period of organogenesis (gestational days 7-17) to pregnant female rats. No treatment-related effects on maternal toxicity or malformations were noted at 25 mg/kg/day (3 times the MRHD based on BSA comparisons). Increased incidences of skeletal variation (14th rib) were noted at 25 mg/kg/day. No treatment-related effects on skeletal variation were noted at 5 mg/kg/day (0.6 times the MRHD based on BSA comparisons).

Subcutaneous doses of 4, 20 and 100 mg/kg/day luliconazole were administered during the period of organogenesis (gestational days 6-18) to pregnant female rabbits. No treatment- related effects on maternal toxicity, embryofetal toxicity or malformations were noted at 100 mg/kg/day (24 times the MRHD based on BSA comparisons)

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In a pre- and postnatal development study in rats, subcutaneous doses of 1, 5 and 25 mg/kg/day luliconazole were administered from the beginning of organogenesis (gestation day 7) through the end of lactation (lactation day 20). In the presence of maternal toxicity, embryofetal toxicity (increased prenatal pup mortality, reduced live litter sizes and increased postnatal pup mortality) was noted at 25 mg/kg/day.

No embryofetal toxicity was noted at 5 mg/kg/day (0.6 times the MRHD based on BSA comparisons). No treatment effects on postnatal development were noted at 25 mg/kg/day (3 times the MRHD based on BSA comparisons).

Lactation

Risk Summary

There is no information available on the presence of luliconazole in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production after topical application of Luliconazole Cream 1 % w/w to women who are breastfeeding Luliconazole Cream 1 % w/w has low systemic absorption. The lack of clinical data during lactation precludes a clear determination of the risk of Luliconazole Cream 1 % w/w to an infant during lactation. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Luliconazole Cream 1 % w/w and any potential adverse effects on the breastfed infant from Luliconazole Cream 1 % w/w or from the underlying maternal condition.

Pediatric Use

The safety and effectiveness of Luliconazole Cream 1 % w/w in pediatric patients 12 to <18 years of age with tinea pedis and tinea cruris have been established by evidence from well- controlled trials in adult and pediatric subjects and a pharmacokinetic (PK) study in pediatric subjects.

The safety and effectiveness of Luliconazole Cream 1 % w/w in pediatric patients 2 to <18 years of age with tinea corporis have been established by evidence from a well-controlled trial in pediatric subjects.

Geriatric Use

Of the total number of subjects in clinical studies of Luliconazole Cream 1 % w/w, 8% were 65 and over, while 1.4% were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience

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has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

4.7 Effects on ability to drive and use Machines:

LULICOR CREAM has no or negligible influence on the ability to drive and use machines.

4.8 Side effects:

Clinical Trials Experience:

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In three phase 3 clinical trials, 616 subjects were exposed to Luliconazole cream 1 % w/w: 305 with interdigital tinea pedis and 311 subjects with tinea cruris. Subjects with interdigital tinea pedis or tinea cruris applied Luliconazole cream 1 % w/w or vehicle cream once daily for 14 days or 7 days, respectively, to affected and adjacent areas. During clinical trials with Luliconazole cream 1 % w/w the most common adverse reactions were application site reactions which occurred in less than 1 % of subjects in both the Luliconazole cream 1 % w/w and vehicle arms. Most adverse reactions were mild in severity.

A post-approval clinical trial was conducted in 75 subjects age 2 to <18 years old with tinea corporis. The adverse reactions in the Luliconazole cream 1 % w/w treated population were similar to the vehicle treated population.

Postmarketing Experience:

The following adverse reactions have been identified during postmarketing use of Luliconazole cream 1 % w/w: contact dermatitis and cellulitis. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions to report any suspected adverse reactions to the National Regulatory Agents.

4.9 OVERDOSAGE

Not reported

5. Pharmacological Properties:

5.1 Pharmacodynamic Properties:

At therapeutic doses, Luliconazole Cream 1 % w/w is not expected to prolong QTc to any clinically relevant extent

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5.2 Pharmacokinetic Properties

Luliconazole is the R enantiomer of a chiral molecule. The potential for interconversion 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 PK 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 % w/w 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 ± 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 Cmax (Tmax) 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 ± SD Cmax was 4.91 ± 2.51 ng/mL after the first dose and 7.36 ± 2.66 ng/mL after the final dose.

The mean Tmax 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 AUC, was 85.1 ± 43.69 ng*hr/mL after the first dose and 121.74 ± 53.36 ng*hr/mL after the final dose.

PK data of luliconazole measured in adolescent subjects (12 to <18 years of age) with moderate to severe interdigital tinea pedis or moderate to severe tinea cruris as well as in subjects 2 to <18 years of age with tinea corporis are described in Specific Populations below.

Specific Populations

PK of luliconazole was assessed in 30 adolescent subjects 12 to <18 years of age with moderate to severe interdigital tinea pedis (N=15) or moderate to severe tinea cruris (N=15). Subjects with tinea pedis applied approximately 3 grams of Luliconazole Cream 1 % w/w once daily to the affected area and adjacent skin for 15 days, while subjects with tinea cruris applied Luliconazole Cream 1 % w/w once daily to the affected and adjacent skin for 8 days.

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Generally, the systemic exposure of luliconazole was greater in the subjects with tinea cruris than tinea pedis. In subjects with tinea pedis, the systemic concentrations of luliconazole were quantifiable in all the subjects on Day 8 and Day 15. The mean ± SD Cmax was 1.80 ± 1.86 ng/mL after the first dose on Day 1, and 3.93 ± 1.67 ng/mL and 3.27 ± 1.71 ng/mL on Days 8 and 15, respectively. The mean ± SD AUC0-24 was 20.47 ± 14.47 ng*hr/mL after the first dose on Day 1, and 64.94 ± 32.47 ng*hr/mL and 60.38 ± 37.92 ng*hr/mL on Days 8 and Day 15, respectively. Like in adult subjects, the mean plasma concentrations of luliconazole in adolescent subjects on Days 8 and 15 were similar and fluctuated little during a 24-hour interval. In subjects with moderate to severe tinea cruris, the systemic concentrations of luliconazole were quantifiable in all the subjects on Day 8. The mean ± SD Cmax was 9.80 ± 5.94 ng/mL after the first dose (Day 1) and 15.40 ± 13.62 ng/mL after the last dose (Day 8). The mean ± SD AUC was 157.07 ± 92.18 ng*hr/mL and 266.06 ± 236.07 ng*hr/mL, after the first dose (Day 1) and the last dose (Day 8).

In subjects with tinea corporis, the systemic concentrations of luliconazole were assessed at pre-dose and at 6 hours post-dose on the last day of treatment following once daily treatment with Luliconazole Cream 1 % w/w.

1% for 7 days. The systemic concentrations were quantifiable in all the 12 subjects and the mean ± SD daily dose of Luliconazole Cream 1 % w/w was 2.84 ± 1.82 g. The mean ± SD concentrations of luliconazole at 15 minutes prior to dosing and at 6 hours post-dose on Day 7 were 4.63 ± 2.93 ng/mL and 4.84 ± 3.33 ng/mL, respectively.

5.3 Preclinical safety Data:

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies to evaluate the carcinogenic potential of Luliconazole Cream 1 % w/w 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

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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 (0.1× MRHD based on BSA comparisons).

6. Pharmaceutical Particulars:

6.1 List of excipients:

Sr. No.	Ingredients	Specification
1.	Cetostearyl Alcohol	BP
2.	Cetomacrogol Emulsifying Wax 1000 (Hydol20)	BP
3.	White Soft Paraffin	BP
4.	Hard Paraffin	BP
5.	Light Liquid Paraffin	BP
6.	Butylated Hydroxyanisole	BP
7.	Butylated Hydroxytoluene	BP
8.	Purified Water	BP
9.	Disodium Edetate	BP
10.	Methyl Hydroxybenzoate	BP
11.	Sodium Dihydrogen Phosphate	BP
12.	Anhydrous Disodium Hydrogen Phosphate	BP
13.	Propylene Glycol	BP
14.	Benzyl Alcohol	BP

6.2 Incompatibilities: Not known.

6.3 Shelf life: 24 Months

6.4 Special precautions for storage:

Store below 30°C. Protect from light. Do not freeze. Keep medicine out of reach of children.

6.5 Nature and contents of container:

15 gm Lami tube. Such 1 tube to be packed in a carton along with pack insert.

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6.6 Special Precaution for Disposal and other handling:

None

7. Marketing authorization holder and manufacturing site addresses:

7.1 Marketing authorization holder:

Company name: Coral Laboratories Ltd.
#3B, Patanwala Compound, Opp. Shreyas Cinema,
L.B.S. Marg, Ghatkopar (West), Mumbai – 400 086,
INDIA

7.2 Manufacturing site address

(Company) Name: CORAL LABORATORIES LIMITED

Address	:	Plot No.27-28, Pharmacity, Selaqui,
		Dehradun-248 011, Uttarakhand.
		INDIA.
Email	:	exports@corallab.com

8. Marketing Authorization Numbers

CTD13079

9. Date of first Registration /renewal of the Registration:
11/12/2025

10. Date of revision of the text:

11/12/2025

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