Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
Lulyera Cream

2. Qualitative and quantitative composition
Luliconazole 1%w/w

For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Cream-Semisolid dosage form

4. Clinical particulars

4.1 Therapeutic indications
Luliconazole Cream 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.

4.2 Posology and method of administration
For topical use only. Luliconazole Creamis not for ophthalmic, oral, or intravaginal use.

- When treating interdigital tinea pedis, a thin layer of Luliconazole Cream should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily for two (2) weeks.
- When treating tinea cruris or tinea corporis, Luliconazole Cream should be applied to the affected area and approximately 1 inch of the immediate surrounding area(s) once daily for one (1) week.

4.3 Contraindications
None

4.4 Special warnings and precautions for use

- Tell your doctor and pharmacist if you are allergic to Luliconazole, any other medications, or any of the ingredients in Luliconazole cream. Ask your pharmacist for a list of the ingredients.
- Tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking.
- Tell your doctor if you have or have ever had any medical condition.
- Tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while using Luliconazole, call your doctor.

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

4.6 Pregnancy and Lactation

Pregnancy

Pregnancy Category C.

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

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 Cream, 1% is administered to women who are breastfeeding.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. When driving vehicles and operating machinery the possibility of adverse reactions such as dizziness, visual disturbances and hearing loss (see Section 4.8), which may occur in some instances, must be taken into account.

4.8 Undesirable effects

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

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems' to the respective National Regulatory Authorities.

4.9 Overdose

No data available

5. Pharmacological properties

5.1 Pharmacodynamic properties

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

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.

5.3 Preclinical safety data

The following adverse reactions have been identified during post marketing use of Luliconazole cream, 1%: 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.

6. Pharmaceutical Particulars

6.1 List of Excipients

Luliconazole IHS
Benzyl Alcohol BP
Crodamol IPM IHS
Arlamol-M812(MCT) IHS
Propylene Glycol BP
Sepenio P 600 IHS
Buyylated hydroxyl Toluene BP
Trancutol P USP
Purified Water USP

6.2 Incompatibilities

None known

6.3 Shelf-Life

24 months

6.4 Special Precautions for storage

Store below 30°C. Do not freeze

6.5 Nature and Content of container

20 g tube is packed in carton.

6.6 Special precautions for disposal and other handling

Not applicable

7. Marketing Authorization Holder

Surgilinks building,
Surgilink's Mombasa Road, Nairobi

P.O Box 14461-00800, Nairobi-Kenya

8. Marketing Authorization Number
H2021/CTD8428/16929

9. Date of first authorization/renewal of the authorization
2021 September 20

10. Date of revision of the text
2021 September 20