Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
KTC Cream

2. Qualitative and quantitative composition
Ketoconazole 2%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
For topical application in the treatment of dermatophyte infections of the skin such as tinea corporis, tinea cruris, tinea manus and tinea pedis infections due to Trichophyton spp, Microsporon spp and Epidermophyton spp. Ketoconazole 2% cream is also indicated for the treatment of cutaneous candidosis (including vulvitis), tinea (pityriasis) versicolor and seborrhoeic dermatitis caused by Malassezia (previously called Pityrosporum) spp.

4.2 Posology and method of administration
Ketoconazole cream is for use in adults.
Ketoconazole 2% cream should be applied gently on the affected areas depending on the severity of the infection or as directed by Physician.
The treatment should be continued until a few days after the disappearance of all signs and symptoms.
Paediatrics There are limited data on the use of ketoconazole 2% cream in paediatric patients.

4.3 Contraindications
Ketoconazole 2% cream is contra-indicated in patients with a known hypersensitivity to any of the ingredients or to ketoconazole itself.

4.4 Special warnings and precautions for use
Ketoconazole 2% cream is not for ophthalmic use.

If co-administered with a topical corticosteroid, to prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids it is recommended to continue applying a mild topical corticosteroid in the morning and to apply Ketoconazole 2% cream in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2-3 weeks.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed.

4.6 Pregnancy and Lactation

There are no adequate and well-controlled studies in pregnant or lactating women. Data on a limited number of exposed pregnancies indicate no adverse effects of topical ketoconazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of ketoconazole.

Plasma concentrations of ketoconazole are not detectable after topical application of Ketoconazole 2% Cream to the skin of non-pregnant humans. There are no known risks associated with the use of Ketoconazole 2% Cream in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

KTC 2% cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The safety of ketoconazole cream was evaluated in 1079 subjects who participated in 30 clinical trials. Ketoconazole cream was applied topically to the skin. Based on pooled safety data from these clinical trials, the most commonly reported (≥1% incidence) adverse reactions were (with % incidence): application site pruritus (2%), skin burning sensation (1.9%), and application site erythema (1%).

Including the above-mentioned adverse reactions, the following table displays adverse reactions that have been reported with the use of ketoconazole cream from either clinical trial or postmarketing experiences. The displayed frequency categories use the following convention:

Not Known (cannot be estimated from the available clinical trial data).

System Organ Class	**Adverse Reactions**		
	Frequency Category		
	Common (≥1/100 to <1/10)	**Uncommon** (≥1/1,000 to <1/100)	**Not Known**
Immune System Disorders		Hypersensitivity	
Skin and Subcutaneous Tissue Disorders	Skin burning sensation	Bullous eruption Dermatitis contact Rash Skin exfoliation Sticky skin	Urticaria
General Disorders and Administration Site Conditions	Application site erythema Application site pruritus	Application site bleeding Application site discomfort Application site dryness Application site inflammation Application site irritation	

		Application site paresthesia Application site reaction	

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

Topical Application Excessive topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment. Ingestion In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Usually ketoconazole cream acts rapidly on pruritus, which is commonly seen in dermatophyte and yeast infections, as well as skin conditions associated with the presence of Malassezia spp. This symptomatic improvement is observed before the first signs of healing are observed.
Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antimycotic activity against dermatophytes such as Trichophyton spp., Epidermophyton floccosum and Microsporum spp. and against yeasts, including Malassezia spp. and Candida spp. The effect on Malassezia spp. is particularly pronounced.

5.2 Pharmacokinetic properties

Plasma concentrations of ketoconazole were not detectable after topical administration of Ketoconazole 2% cream in adults on the skin. In one study in infants with seborrhoeic dermatitis (n = 19), where approximately 40 g of Ketoconazole 2% cream was applied daily on 40% of the body surface area, plasma levels of ketoconazole were detected in 5 infants, ranging from 32 to 133 ng/mL

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6. Pharmaceutical Particulars

6.1 List of Excipients

Propyl paraben
Propylene Glycol
Para Chloro Meta Cresol
Cetamacrogol 1000
Light Liquid Paraffin
White Petroleum Jelly

Ceto Stearyl Alcohol
Purified Water

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
30 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/CTD8429/16932

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

10. Date of revision of the text
2021 September 20