SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)	
Product name	**NAZOLE CREAM** **Ketoconazole USP 2%w/w Cream**

1. Name of the medicinal product

Nazole Cream

2. Qualitative and quantitative composition

Ketoconazole USP 2%w/w in cream (water washable) base and excipients

3. Pharmaceutical form

Cream

White semi solid, non-gritty cream, packed in a collapsible tubes and contained in a unit box with literature insert.

4. Clinical particulars

4.1 Therapeutic indications

Nazole cream is indicated 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. Nazole cream is also indicated for the treatment of cutaneous cadidosis (including vulvitis), tinea (pityriasis) versicolor and seborrhoeic dermatitis caused by Malassezia spp.

4.2 Dosage and Administration

Method of Administration: Cutaneous administration.
Nazole cream should be applied to the affected areas twice daily. The usual duration of treatment for mild infections is one week. For more severe or extensive infections (eg involving the sole or sides of the feet) treatment should be continued until a few days after all signs and symptoms have disappeared in order to prevent relapse.

For other infections:
Nazole cream should be applied to the affected areas once or twice daily, depending on the severity of the infection.
The treatment is tinea versicolor 2 – 3 weeks, tinea corporis 3 – 4 weeks.
The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks. General measures in regard to hygiene should be observed to control sources of infection or reinfection. Seborrhoeic dermatitis is a chronic condition and relapse is highly likely.

Paediatrics
There are limited data on the use of ketoconazole 2% cream in paediatric patients.

4.3 Contraindications

Nazole cream is contra-indicated in patients with a known hypersensitivity to any of the ingredients or ketoconazole itself.

Nazole 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 Nazole cream in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapyover a period of 2 – 3 weeks.

4.4 Interaction with other medicinal products and other forms of interaction
None known.

4.5 Fertility, pregnancy and lactation
There are no known risk associated with the use of Nazole cream in pregnancy or lactation.

4.6 Effects on ability to drive and use machines
None.

4.7 Side effects
The most commonly reported adverse reactions are: application site pruritus (2%), skin burning sensation (1.9%) and application site erythema (1%).

4.8 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
Pharmacotherapeutic Group: Imidazole and triazole derivatives; ATC code: D01 AC08

Ketoconazole has a potent antimycotic action against dermatophytes and yeasts. Ketoconazole cream acts rapidly on the pruritus, which is commonly seen in dermatophyte and yeast infections. This symptomatic improvement often occurs before the first signs of healing are observed.

A study in 250 patients has shown that application twice daily for 7 days of ketoconazole 2% cream vs clotrimazole 1% cream for 4 weeks on both feet demonstrated efficacy in patients with tinea pedis (athlete's foot) presenting lesions between the toes.

The primary efficacy endpoint was negative microscopic KOH examination at 4 weeks. Ketoconazole 2% treatment showed equivalent efficacy to 4 weeks clotrimazole 1% treatment. There was no evidence of relapse following treatment with ketoconazole cream at 8 weeks.

5.2 Pharmacokinetic properties
Plasma concentrations of ketoconazole were not detectable after topical administration of ketoconazole cream in adults on the skin. In one study in infants with seborrhoeic dermatitis (n = 19), where approximately 40 g of ketoconazole 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.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)	
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6. Pharmaceutical particulars

6.1 List of excipients

Liquid paraffin

Petroleum jelly

Cetostearyl alcohol

Cetomacrogol 1000

Monopropylene glycol

Benzyl alcohol

Sodium Dihydrogen Phosphate

Purified Water

6.2 Incompatibilities

None.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Keep in a dry place below 30^0C

Do not freeze.

6.5 Nature and contents of the container:

20gm packed in Collapsible Aluminum Tube contained in a unit box with literature Insert

6.6 Special precautions for disposal and other handling

No special requirements.

7. Registrant:

Company name: LABORATORY & ALLIED LTD

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P.O BOX 42875, CODE 00100 NAIROBI, Country: KENYA

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SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)	
Product name	**NAZOLE CREAM** **Ketoconazole USP 2%w/w Cream**

8. Manufacturer

Company name: LABORATORY & ALLIED LTD

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