1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME: Ketaconazole 2.0%

BRAND NAME: Ketacon Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each filled tube contains:
Ketaconazole……2.0%
Excipients……q.s

For complete list of excipients refer section 6.1.

3. *PHARMACEUTICAL FORM*:

Cream
White creamy and very smooth when applied on the skin

4. *CLINICAL PARTICULARS*

For the treatment of the following mycotic infections of the skin: tinea pedis and tinea cruris

4.2 Posology and method of administration:

Ketoconazole cream is for use in adults.

For the treatment of tinea pedis (athlete's foot) and tinea cruris (dhobie itch).

Tinea cruris and tinea pedis: It is recommended that Daktarin Intensiv Cream be applied once or twice daily to cover the affected and immediate surrounding area.

The usual duration of treatment is tinea cruris 2-4 weeks, tinea pedis 4-6 weeks.

Treatment should be continued, until a few days after disappearance of all symptoms. The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks of treatment.

Method of administration: Topical administration

Paediatric patients

The safety and efficacy of Daktarin Intensive Cream in children (17 years and younger) has not been established.

4.3 Contraindications:

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4 Special warning and precautions for use

Ketacon cream is not for ophthalmic use.

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 Ketacon cream in the evening, and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks.

This medicine contains acetyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). Also contains propylene glycol which may cause skin irritation.

4.5 Drug Interactions

None known.

4.6 Pregnancy &Lactation

There are no adequate and well-controlled studies in pregnant or lactating women. To date, no other relevant epidemiological data are available. 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 Ketaconto the skin of non-pregnant humans (See Pharmacokinetic properties, section 5.2). There are no known risks associated with the use of Ketaconin pregnancy or lactation.

4.7 Effects on ability to drive and use machines:

This medicine has no influence on the ability to drive and use machines

4.8 Adverse 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) ADRs were (with % incidence): application site pruritus (2%), skin burning sensation (1.9%), and application site erythema (1%). Including the above-mentioned adverse drug reactions (ADRs), the following table displays ADRs that have been reported with the use of ketoconazole cream from either clinical trial or post-marketing experiences. The displayed frequency categories use the following convention:

Very Common	(≥1/10)
Common	(≥1/100 to <1/10)
Uncommon	(≥1/1,000 to <1/100)
Rare	(≥1/10,000 to <1/1,000)

Very rare (<1/10,000)

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

System Organ Class	Adverse Drug 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 paraesthesia Application site reaction	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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.

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: D01AC08

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.

6. *PHARMACEUTICAL PARTICULARS*

6.1 List of excipients

Ketoconazole USP
C.M Emulsifying wax BP
White Petroleum Jelly BP
Liquid Paraffin (Light) BP
Chlorocresol BP
Sodium Phosphate BP
Sodium Metabisulphate BP
Di-sodium EDTA BP
Propylene Glycol BP
Fragrance (Blue Water)

6.2 Incompatibilities

None known.

6.3 Shelf Life

3 years

6.4 Special precautions for storage:

Store in a cool dry place at a temperature not exceeding 25°C.

Protect from light.

6.5 Nature and contents of container

The cream is filled into tube made of 99.7% aluminum and packed in inner carton along with leaflet. Pack sizes available is 30g

NAFDAC Reg.Number : A4-5364

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal products or waste material should be disposed of in accordance with local requirements.

7. *APPLICANT*

Name of the Applicant:
SAGAR VITACEUTICALS NIGERIA LIMITED

Business Address:
Plot 2, Ladipo Oluwole Street,
Off Oba-Akran Avenue, Ikeja.
Lagos,
NIGERIA

Manufactured by:

SAGAR VITACEUTICALS NIGERIA LIMITED.
Plot 2, Ladipo Oluwole Street,
Off Oba-Akran Avenue, Ikeja.
Lagos,
NIGERIA

8. *WHO PREQUALIFICATION REFERENCE NUMBER*
Not applicable

9. *DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION*
Not applicable

10. ***DATE OF REVISION OF THE TEXT***

Not applicable