GLOWZORAL
(Ketoconazole Cream 2%)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the Medicinal Product

GLOWZORAL (Ketoconazole Cream 2%)

2. Qualitative and Quantitative Composition

Composition

Ketoconazole USP 2% w/w

Cream Base q.s.

3. Pharmaceutical Form

Cream

4. Clinical Particulars

4.1 Therapeutic indications

For the treatment of the following mycotic infections of the skin: tinea pedis, tinea cruris and candidal intertrigo.

4.2 Posology and method of administration

Dosage and Administration

Ketoconazole cream is for use in adults. For the treatment of tinea pedis (athlete's foot) and tinea cruris (dhobie itch) and candidal intertrigo (sweat rash). Tinea cruris, candidal intertrigo and tinea pedis*:* It is recommended that Daktarin Gold 2% 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, candidal intertrigo 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: Cutaneous use.

Paediatric patients: The safety and efficacy of 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.

4.4 Special warning and special precaution for use

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

4.5 Interaction with other medicinal products and form of interaction

None known.

4.6 Pregnancy and lactation

here 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 fetus/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 cream to the skin of non-pregnant humans. There are no known risks associated with the use of cream in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None.

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:

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 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	

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

Pharmacotherapeutic group: Antifungals for Topical Use, Imidazole and triazole derivatives.

ATC Code: D01AC08

Usually ketoconazole cream acts rapidly on pruritus, which is commonly 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.

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 Studies

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.

6.0 PHARMACEUTICAL EXCIPIENTS

6.1 List of excipients

S. NO	INGREDIENTS	GRADE
1.	Ketoconazole	USP
2.	Chlorocresol	BP
3.	Cetomacrogol-1000	BP
4.	Cetostearyl Alcohol	BP
5.	Liquid Paraffin	BP
6.	Propylene Glycol	BP
7.	White Soft Paraffin	BP
8	Butylated Hydroxytoluene	BP
9.	Butylated Hydroxyanisole	BP
10.	Tween 80	BP
11.	Purified Water	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precaution for storage

Store at temperature below 30°C. Protect from light.

6.5 Nature contents of container

20gm tube in a carton

6.6 Instruction for use handling and disposal

Keep out of reach of children.

7. Manufacturer name

ALPA LABORATORIES LIMITED
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8. Marketing Authority

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