SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENERIC: Ketoconazole Cream BP 2% w/w

BRAND NAME: Ketoz

DESCRIPTION:
White Soft cream.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Ketoconazole BP...….....2% w/w

In a cream base.....….q.s.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Semi Solid Dosage Form – Cream.

4.CLINICAL PARTICULARS

4.1 Therapeutic Indication:

It is used for topical treatment of Tinea Crusis and Tinea Corporis caused by dermatomycosis and infection caused by candida species. Candidura and Systemic candidosis.

4.2 Posology and method of administration:

Ketoconazole cream is for use in adults

Tinea pedis:

Ketoconazole cream should be applied to the affected areas twice daily. The usual duration of treatment for mild infections is 1 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:

Ketoconazole cream should be applied to the affected areas once or twice daily, depending on the severity of the infection. The treatment should be continued until a few days after the disappearance of all signs and symptoms. The usual duration of 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.

OR As directed by physician.

Method of administration: Topical (Cutaneous) cream.

4.3 Contraindications:

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

4.4 Warning 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 Drug Interactions

No interaction studies have been performed.

4.6 Fertility Pregnancy & 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:

None.

4.8 Adverse Effects

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 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. 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetomacrogol -1000 BP, Cetostearyl Alcohol BP, Light Liquid Paraffin BP, White Soft Paraffin BP, Propylene Glycol BP, Chlorocresol BP, Disodium Hydrogen Phosphate (Dihydrate) BP, Sodium Dihydrogen Phosphate Dihydrate BP, Disodium Edetate BP, Purified Water BP, Phosphoric Acid BP.

6.2 Incompatibilities

Nil.

6.3 Shelf Life

36 Months.

6.4 Special precautions for storage:

Do not store above 30 °C. Protect from Light. Do not freeze.

Do not accept if seal is broken.

Keep the tube tightly closed after use.

Puncture nozzle seal with piercing point of cap.

Keep the medicine out of reach of children.

6.5 Nature and contents of container

15gm tube further packed in printed carton along with insert.

7. APPLICANT
Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,
Vapi - 396 195. Gujarat, INDIA.