SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
KETOKREM CREAM (Ketoconazole Cream 2.00 %w/w)

2. Qualitative and quantitative composition
Ketoconazole BP .....2.0 % w/w
Cream Base ..... Q.S.
For the full list of excipients see section 6.1

3. Pharmaceutical form
Topical Cream
A white to off white soft cream.

4. Clinical particulars
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. Ketokrem 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.

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

Special warnings and precautions for use
Ketokrem 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 Ketokrem cream in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2-3 weeks.

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

Fertility, 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 Ketokrem cream to the skin of non-pregnant humans. (See Pharmacokinetic properties, section 5.2) There are no known risks associated with the use of Ketokrem cream in pregnancy or lactation.

Effects on ability to drive and use machines

Ketokrem cream has no influence on the ability to drive and use machines.

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	Application site	Application site bleeding	

Administration Site Conditions	erythema Application site pruritus	Application site discomfort Application site dryness Application site inflammation Application site irritation Application site paresthesia Application site reaction	

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

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.

Pharmacokinetic properties

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

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

List of excipients

Propylene Glycol
Stearyl Alcohol
Cetyl Alcohol
Sorbitan Monostearate
Polysorbate 60
Isopropyl Myristate
Sodium Sulfite Anhydrous
Polysorbate 80
Purified water

Incompatibilities

Not applicable.

Shelf life

36 months.

Special precautions for storage

Keep all the medicines out of reach of children. Store at temperature not exceeding 30°C.Do not freeze.

Nature and contents of container

Lami Tube of 30g.

Special precautions for disposal and other handling

No special requirements

ADMINISTRATIVE DATA:

7. Marketing authorization holder

Kremoint Pharma Pvt. Ltd.,

B-8 Additional MIDC, Ambernath

Ambernath (E). Thane 421506

8. Marketing authorisation number(s)

Registration Number: 05370/06691/NMR/2018

9. Date of first authorisation/renewal of the authorisation

Approval Date: 29.09.2020

10. Date of revision of the text

Revision of Text : 29.09.2025