# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT :

DERM KETA Cream (Ketoconazole Cream 2%**)**

## 2. ANATOMIC THERAPEUTIC AND CHEMICAL (ATC) CLASSIFICATION AND DISTRIBUTION CATEGORY:

Pharmacotherapeutic Group : Antifungal
ATC code : D01AC08

## 3. QUALITATIVE AND QUANTITATIVE COMPOSITION

| **ACTIVE** |
|---|
| Ketoconazole |
| **INACTIVE** |
| Propylene Glycol |
| Cetostearyl Alcohol |
| Span 60 (Sorbitan) |
| Polysorbate 60 (tween 60) |
| Polysorbate 80 (Tween 80) |
| Sodium Sulphite |
| Isopropyl Myristate |
| Purified Water |

## 4. PHARMACEUTICAL FORM: Topical Cream.

## 5. CLINICAL PARTICULARS

### 5.1 Therapeutic indications:

Ketoconazole Cream is indicated for the treatment of dermatophyte infections of the skin, tinea corpois, tinea cruris, tinea mamus and tinea pedis due to Tricophyton rubrum, Trichophyton mentagrophytes, Microsporum canis and Epidermophyton floccosum as well as in the treatment of cutaneous candidosis and tinea (pityriasis) versicolor.

Ketoconazole Cream is also indicated for the treatment of seborrhoeic dermatitis, a skin condition related with the presence of pityrosporum ovale.

## 5.2 Posology and method of administration

As directed by Physician.
Ketoconazole Cream should be applied to affected areas once or twice daily. In patients with tinea corporis, tinea cruris, tinea manus, tinea pedis, cutaneous candidosis and seborrhoeic dermatitis and once daily in patients with tinea versicolor. Treatment should be continued for a sufficient period at least until a few days after disappearance of all symptoms. The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks of treatmenr. General measures in regard to hygiene should be observed to control sources of infection or reinfection.

## 5.3 Contraindications

Hypersensitivity to any of its ingredients.

## 5.4 Special warnings and special precautions for use

For external use only. Use only as directed. Keep away from children to avoid accidental poisoning. Keep away from eyes, mucous membrane, and broken or irritated skin. If skin irritants develop or if pain lasts 7 days or more, or if redness is present, discontinue use and consult a physician immediately. Do not swallow. If swallowed induce vomiting, call a physician.

## 5.5 Interaction with other FPPs and other forms of interaction

None.

## 5.6 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 does that are not relevant to the topical administration of Ketoconazole.
Plasma concentrations of Ketoconazole are not detectable after topical application of Ketoconazole Cream 2 % to the skin of non-pregnant humans. There are no known risks associated with the use of Ketoconazole Cream 2% in pregnancy or lactation.

## 5.7 Effects on ability to drive and use machines

No effect on the above. No sedation / drowsiness have been reported.

## 5.8 Undesirable effects

Irritation, pruritus and stinging.

### 5.9 Overdose

If irritation develops, topical antifungal should be discontinued and appropriate therapy instituted.

## 6. PHARMACOLOGICAL PROPERTIES

### 6.1 Pharmacodynamic properties

Ketoconazole, a synthetic imidazole dioxolane, has an antimycotic activity against dermatophytes such as Trichopyton spp. Epidermophyton floccosum and Microsporum spp. and against yeasts. Derm Keta Cream does not produce detectable blood vessels after topical application.

A study in 250 patients has shown that application twice daily for 7 days of Ketoconazole Cream 2% vs. Clotrimazole Cream 1% for 4 weeks on both feet demonstrated efficacy in patients with tinea pedis (Atheletes'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.

### 6.2 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.

### 6.3 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.

## 7. PHARMACEUTICAL PARTICULARS

### 7.1 Incompatibilities

None.

### 7.2 Shelf life

36 months.

### 7.3 Special precautions for storage

Store at a temperature below 30°C.

### 7.4 Nature and contents of container

Printed 10 g aluminium collapsible tube with HDPE cap. Tubes are lacquered with sealed nozzle at one end and open at the other end, white opaque flat bottom caps with a piercing tip.

**7.5 Instructions for use and handling and disposal**

Bulk of Cream is removed from tube and incinerated. Empty tubes and cartons are shred under supervision of expert technical staff.

**7.6 Name and address of manufacturer**

Galentic Pharma (India) Pvt. Ltd.,
R-673, M.I.D.C., T.T.C., Rabale,
Thane-Belapur Road,
Navi Mumbai, India.

**7.7 Name and address of principal**

Galentic Pharma (India) Pvt. Ltd.,
4th Floor, Samruddhi Venture Park,
MIDC Central Road, Andheri (East),
India.

**8 REGISTRATION NUMBER**

04452/06808/REN/2018

**9 CATEGORY FOR DISTRIBUTION**

Not Applicable

**10 DATE OF PUBLICATION OF THIS PACKAGE INSERT**

Not Applicable