

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dermazole 2% Shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of shampoo contains:

Ketoconazole USP 20 mg (2% w/v)

For excipients, see section 6.1

3. PHARMACEUTICAL FORM

Shampoo

Description: Clear viscous liquid of pink to red colour with specific odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Dermazole shampoo is indicated for treatment and prevention of seborrhoeic dermatitis, dandruff and tinea versicolor caused by Pityrosporum fungus.

4.2 Posology and method of administration

For topical administration.

Ketoconazole shampoo 2% is for use in adolescents and adults:

Wash affected areas and leave for 3-5 minutes before rinsing.

Treatment:

Dandruff and seborrhoeic dermatitis: Wash hair twice weekly for 2-4 weeks.

Tinea versicolor: Once daily for a maximum of 5 days.

Prophylaxis:

Dandruff and seborrhoeic dermatitis: Use once every 1-2 weeks.

Tinea versicolor: Once daily for a maximum of 3 days before exposure to sunshine.

4.3 Contraindications

Known hypersensitivity to ketoconazole or any of the excipients.

4.4 Special warnings and precautions for use

In patients who have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Dermazole 2% shampoo, to prevent any potential rebound effect.

Keep out of the eyes. If the shampoo should get into the eyes, they should be bathed with water.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 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 doses that are not relevant to the topical administration of ketoconazole. No effects on the breastfed newborn/infant are anticipated.

Plasma concentrations of ketoconazole were not detectable after topical administration of Ketoconazole Shampoo 2% to the scalp of non-pregnant humans. Plasma levels were detected after topical administration of Ketoconazole Shampoo 2% on the whole body. There are no known risks associated with the use of Ketoconazole Shampoo 2% in pregnancy or lactation.

4.6 Effects on ability to drive and use machines

Not relevant.

4.7 Undesirable effects

The following table displays ADRs that have been reported with the use of ketoconazole 2% Shampoo from either clinical trial or post marketing experiences.

The displayed frequency categories use the following convention: Very common ($\geq 1/10$), Common ($\geq 1/100$ to $< 1/10$), Uncommon ($\geq 1/1,000$ to $< 1/100$), Rare ($\geq 1/10,000$ 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		
	Uncommon ($\geq 1/1,000$ to $< 1/100$)	Rare ($\geq 1/10,000$ to $< 1/1,000$)	Not Known
Immune System Disorders		Hypersensitivity	
Nervous System Disorders		Dysgeusia	
Infections and Infestations	Folliculitis		
Eye Disorders	Increased lacrimation	Eye irritation	
Skin and Subcutaneous Tissue Disorders	Alopecia Dry skin Hair texture abnormal Rash Skin burning sensation	Acne Dermatitis contact Skin disorder Skin	Angioedema Urticaria Hair colour changes
General Disorders and Administration Site Conditions	Application site erythema Application site irritation Application site pruritus Application site reaction	Application site hypersensitivity Application site pustules	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 EFDA yellow Card Scheme, online at <https://primaryreporting.who-umc.org/ET> or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.8 Overdose

In the event of accidental ingestion, supportive and symptomatic measures should be carried out. In order to avoid aspiration, neither emesis nor gastric lavage should be instigated.

5. Pharmacological properties.

Pharmacotherapeutic group: Antifungals for topical use, Imidazole and triazole derivatives.

ATC Code: D01AC08

5.1 Pharmacodynamics

Ketoconazole is an imidazole-dioxolane antimycotic, active against yeasts, including *Malassezia* and dermatophytes. Its broad spectrum of activity is already well known.

5.2 Pharmacokinetics

Plasma concentrations of ketoconazole were not detectable after topical administration of Dermazole 2% shampoo on the scalp. Plasma levels were detected after topical administration of Dermazole 2% shampoo on the whole body.

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

Sodium lauryl ether sulphate, Cocodiethanolamide, Propylene glycol, Disodium monolauryl ether sulfosuccinates, Macrogol 120 methyl glucose dioleate, Conc. hydrochloric acid, Sodium chloride, Sodium hydroxide pellets, Butylated hydroxyl toluene, Ponceau 4R, Imidurea, Fragrance CK D00923 & Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C in a dry place. Protected from direct sunlight. Keep out of reach of children.

6.5 Nature and contents of container

50 ml or 100 ml shampoo in HDPE bottles. Each bottle in PVC shrink wrap packed in a carton along with pack insert.

6.6 Special precautions for disposal and other handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

Kusum Healthcare Pvt. Ltd.
SP-289(A), RIICO Industrial Area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan) India

8. MARKETING AUTHORISATION NUMBER(S)

04989/07179/NMR/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 February 2020

10. DATE OF REVISION OF THE TEXT

08/2023

11. REFERENCES

SmPC published on electronic medicines compendium
<https://www.medicines.org.uk/emc#gref>

The MHRA published product information
<https://products.mhra.gov.uk/>

Human medicine European public assessment report
<https://www.ema.europa.eu/en/medicines>