

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ketoconazole 2% Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoconazole 2% w/w (each gram contains 20 mg).

Excipient(s) with known effect:
Sodium Lauryl Ether Sulfate 24% w/w

For a full list of excipients, see 6.1

3 PHARMACEUTICAL FORM

Shampoo

Red orange colour liquid or suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of infections in which the yeast *Malassezia* (previously called *Pityrosporum*) is likely to be involved, such as dandruff and seborrhoeic dermatitis. Treatment of tinea (pityriasis) versicolor.

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 1-5 days.

Prophylaxis:

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

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Ketoconazole 2% shampoo, to prevent any potential rebound effect.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

Excipient warnings:

This medicine contains 24% w/w sodium lauryl ether sulfate in each application. Sodium lauryl ether sulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed

4.6 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. No effects on the breastfed newborn/infant are anticipated. See Pharmacokinetic properties, section 5.2

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

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

The safety of ketoconazole 2% shampoo was evaluated in 2890 subjects who participated in 22 clinical trials. Ketoconazole 2% shampoo was administered topically to the scalp and/or skin. Based on pooled safety data from these clinical trials, there were no ADRs reported with an incidence $\geq 1\%$.

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 ($\geq 1/10,000$ and $< 1/1,000$)	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 exfoliation	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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 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

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole and triazole derivatives

ATC Code: D01AC08

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

5.2 Pharmacokinetic properties

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

Cocodiethanolamide
Disodium Laureth Sulfosuccinate
Allura red AC (E129)
Hydrochloric Acid
Imidurea
Laurdimonium Hydroxypropyl Hydrolyzed Collagen
PEG-120 Methyl Glucose Dioleate
Sodium Chloride
Sodium Lauryl Ether Sulphate
Sodium Hydroxide
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years
After first opening use within 60 days.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.
Store in the original pack to protect from light.

6.5 Nature and contents of container

High-density polyethylene bottles, containing 120 ml shampoo.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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Northampton
England NN7 4PP
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 58839/0111

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/03/2026

10 DATE OF REVISION OF THE TEXT

09/03/2026