

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

KETOZOL 2% w/w Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoconazole 2 % w/w (20 mg/g).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo

Clear, reddish solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of seborrhoeic dermatitis of the scalp in adults.

4.2 Posology and method of administration

For topical use.

The affected areas are to be washed with shampoo and rinsed after 3-5 minutes.

Seborrhoeic dermatitis:

Treatment: Twice weekly for 2-4 weeks.

Prophylaxis: Once a week or every two weeks.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

Seborrhoeic dermatitis is often associated with increased loss of hair which has also been reported –although in rare cases – in treatment with Ketozol Shampoo. Avoid contact with the eyes. If the shampoo should get into the eyes, they should be bathed with water.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Ketozol Shampoo, to prevent any potential rebound effect.

4.5 Interaction with other medicinal products and other forms of interaction

The systemic absorption of topically applied ketoconazole is minimal and systemic interaction with other medicinal products is unlikely.

4.6 Fertility, pregnancy and lactation

There are no adequate and well-controlled studies in pregnant or lactating women. Studies in animals have shown reproductive toxicity in high doses, indicating that ketoconazole may cause harmful effects with respect to foetal development. However, 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.

Ketozol has not been found in plasma after chronic shampooing, and lactation may continue during treatment.

There are no known risks associated with the use of Ketozol Shampoo in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Ketozol Shampoo has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The safety of ketoconazole shampoo 2% was evaluated in 2980 subjects who participated in 22 clinical trials. Ketoconazole shampoo 2% 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 adverse drug reactions (ADRs) that have been reported with the use of ketoconazole shampoo 2% from either clinical trial or postmarketing 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 ($<1/10,000$); and 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 $<1/100$)	Not Known
Nervous System Disorders	Dysgeusia	
Infections and Infestations	Folliculitis	
Eye Disorders	Eye irritation Increased lacrimation	
Skin and Subcutaneous Tissue Disorders	Acne Alopecia Dermatitis contact Dry skin Hair texture abnormal Rash Skin burning sensation Skin disorder Skin exfoliation	Urticaria Hair colour changes
General Disorders and Administration Site Conditions	Application site erythema Application site irritation Application site hypersensitivity Application site pruritus Application site pustules Application site reaction	

4.9 Overdose

When Ketozol Shampoo is only used for topical administration, no overdose is expected.

In the event of accidental ingestion, supportive and symptomatic measures should be carried out. To avoid aspiration, emesis or gastric lavage should not be performed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole derivatives triazole, ATC code: DO1AC08

The active substance of Ketozol shampoo is ketoconazole which is an imidazole compound. Ketoconazole is an antimycotic with fungistatic effect on e.g. Trichophyton, Epidermophyton, Microsporum spp. and yeast fungi (Candidia, Pityrosporum) when topically applied. Ketoconazole shampoo relieves itching and squamation, usually occurring in case of seborrhoeic dermatitis.

5.2 Pharmacokinetic properties

Percutaneous absorption of ketoconazole Shampoo is negligible since the concentration in the blood - even after long-term use - was below the detection limit of the analysis method (≤ 5 ng/ml). Therefore, no systemic effect is to be expected.

5.3 Preclinical safety data

There are no preclinical safety data considered relevant with regards to the assessment of the safety of topically applied ketoconazole.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium lauryl ether sulphate
Disodium monolauryl ether sulphosuccinate
Magrogol 120 methyl glucose dioleate
Macrogol 7 glyceryl cocoate
Imidurea
Laurdimonium hydroxypropyl hydrolysed animal collagen
Coconut fatty acid diethanolamide
Sodium hydroxide
Sodium chloride
Ponceau 4R (E124)
Hydrochloric acid, concentrated
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

HDPE bottle with PP cap inserted in a carton.

Pack sizes: 60 ml and 120 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

ROWEX LTD

Bantry

Co Cork

8 MARKETING AUTHORISATION NUMBER

PA 711/76/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd December 2005

Date of last renewal: 23rd December 2008

10 DATE OF REVISION OF THE TEXT

March 2012