Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

KETOZOL 2% w/w Dandruff Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoconazole 2 % (20 mg/g).

Excipient with known effect: Each gram shampoo contains max. 0,004 mg potassium sorbate.

For the 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 in the scalp in adults and adolescents.

4.2 Posology and method of administration

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

Seborrhoeic dermatitis:
Treatment: Twice weekly for 2-4 weeks.
Prophylaxis: Once a week or every two weeks.

Ketozol Dandruff Shampoo 2% is for use in adolescents and adults.

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 Dandruff Shampoo.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Ketozol Dandruf Shampoo 2%, to prevent any potential rebound effect.
Avoid contact with the eyes. If the shampoo should get into the eyes, they should be bathed with water.

Ketoconazole 20 mg/g shampoo contains potassium sorbate.
Potassium sorbate may cause local skin reactions (e.g. contact dermatitis).

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. There are no known risks associated with the use of ketoconazole shampoo in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Ketozol Dandruff 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 ≥ 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 (≥ 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); and not known (cannot be estimated form the available clinical trial data).

System Organ Class	**Adverse Drug Reactions**		
	Frequency Category		
	Uncommon (≥ 1/1,000 to <1/100)	**Rare** (≥1/10,000 to <1/1,000)	**Not Known**
Immune System Disorder		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	Angioderma 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

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 derivates and triazole, ATC code: D 01 AC 08

The active substance of Ketozole dandruff shampoo is ketoconazole which is an imidazole compound. Ketoconazole is an antimycotic with fungistatic effect on eg. Trichophyton, Epidermophyton, Microsporum spp. and yeast fungi (Candida, Pityrosporum) when topically applied. Ketoconazole shampoo relieves itching and squamation, usually occuring 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 data considered relevant with regards to the assessment of the safety evaluation 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
Lauryldimonium hydroxypropyl hydrolysed animal collagen (consisting of: water, lauryldimonium, hydroxypropyl hydrolised collagen, phenoxyethanol, potassium sorbate, sodium chloride)
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 25ºC.

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

PA0711/076/002

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

October 2016