Summary of Product Characteristics

1. Name of the medicinal product

Ketozol shampoo

2. Qualitative and quantitative composition

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

Excipient(s) with known effect:
Sodium lauryl ether sulfate 380 mg/gram
For a full list of excipients, see 6.1

3. Pharmaceutical form

Orange to red viscous shampoo.

4. Clinical particulars

4.1 Therapeutic indications

Topical treatment of seborrhoeic dermatitis including dandruff resulting from proven fungal infection including pityriasis versicolor.

4.2 Posology and method of administration

For topical use only.

Ketoconazole shampoo 2% is intended for use in adults and adolescents over 12 years of age:

The frequency of use depends on the infection type:

Seborrhoeic dermatitis and Dandruff:	Twice weekly for 2 to 4 weeks.
Pytriasis versicolor:	Once daily for 1-5 days.

The infected areas of the skin or the scalp should be thoroughly washed with Ketozol shampoo, which should be left on the skin/scalp for 3-5 minutes before rinsing. It is important to soap thoroughly the scalp and the skin itself, and not just the hair. Usually, a palmful of Ketozol shampoo suffices for one wash.

4.3 Contraindications

Hypersensitivity to the active substance ketoconazole or any of the excipients listed in section 6.1.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Ketozol shampoo, to prevent any potential rebound effect.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 380 mg/g 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 ≥1%.

The following table displays ADRs that have been reported with the use of Ketoconazole 2% Shampoo 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)

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 and <1/1,000)	**Not Known**
Immune System disorders		Hypersensitvity	
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	Acne Dermatitis contact Skin disorder Skin exfoliation	Angioedema Urticaria Hair colour changes

	Skin burning sensation		
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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/
Additionally, you can also report to www.perrigo-pharma.co.il.

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 Ketozol shampoo on the scalp. Plasma levels were detected after topical administration of Ketozol 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

Standapol ES-2 (Sodium lauryl ether sulfate), Stepan-Mild SL-3 (Disodium Laureth sulphosuccinate), Incromed CA (Coconut fatty acid diethanolamide), Croquate L (Laurdimonium Hydroxypropyl Hydrolysed collagen), Sodium Chloride USP, Glucamate DOE-120 (PEG-120 Methyl Glucose Dioleate), Hydrochloride acid NF, Sodium hydroxide NF, Germall 115 (Imidurea NF), FD&C Red #40, Water purified (USP)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C. Protect from light

6.5 Nature and contents of container

High density polyethylene bottles, containing 120 ml shampoo.

6.6 Special precautions for disposal and other handling

No special requirements

7. Manufacturer and marketing authorization holder

Perrigo Israel Pharmaceuticals Ltd. P.O.B. 16 Yeruham

8. Registration number:

138-73-31583-00

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