SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nizoral 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

Pink viscous shampoo.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Nizoral 2% shampoo, to prevent any potential rebound effect.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 ≥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 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 Nizoral 2%shampoo on the scalp. Plasma levels were detected after topical administration of Nizoral 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.

6.1 List of excipients

Sodium lauryl ether sulfate
Disodium monolauryl ether sulphosuccinate
Coconut fatty acid diethanolamide
Laurdimonium hydrolysed animal collagen
Macrogol 120 methyl glucose dioleate
Sodium chloride
Concentrated hydrochloric acid
Imidurea
Sodium hydroxide

Erythrosine sodium (E217)
Water purified (Ph. Eur.)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

High density polyethylene bottles, containing 120 ml shampoo.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd., Linthwaite, Huddersfield, HD7 5QH, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0451

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/06/2008

10 DATE OF REVISION OF THE TEXT

23/10/2020