Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nizoral Dandruff 20mg/g Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of shampoo contains 20mg of ketoconazole
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo
Pink, viscous shampoo

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the prevention and treatment of infections in which *Malassezia* (previously called *Pityrosporum*) infection may be a factor, such as seborrhoea capitis, and seborrhoeic dermatitis of the body.

4.2 Posology and method of administration

Nizoral Dandruff Shampoo is for use in adults and adolescents aged 12 years and over.

Seborrhoea capitis

Apply the shampoo to the affected scalp, leave for three minutes, then rinse.

Seborrhoeic dermatitis

Wash the affected areas with shampoo and leave for 3 to 5 minutes before rinsing.

Treatment should be repeated twice weekly for 2 to 4 weeks.

For prophylaxis use once, every 1 to 2 weeks.

Paediatric population
The safe and effective use of Nizoral Dandruff Shampoo in infants and children under the age of 12 years has not been established.

Method of administration

Cutaneous. Usually, a palmful of shampoo suffices for one wash.

4.3 Contraindications

Use in patients hypersensitive to any of the ingredients.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Nizoral Dandruff Shampoo, to prevent any potential rebound effect.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

4.5 Interaction with other medicinal products and other forms of interactions

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 Ketoconazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity following oral administration of ketoconazole. (see Preclinical safety data, section 5.3).

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

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The safety of NIZORAL Shampoo 2% was evaluated in 2980 subjects who participated in 22 clinical trials. NIZORAL 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 ADRs that have been reported with the use of NIZORAL 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), Not known (cannot be estimated from the available clinical trial data).

System Organ Class	Adverse Drug Reactions Frequency Category	
	Uncommon (≥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	Angioedema,Urticaria Hair colour changes
General Disorders and Administration Site Conditions	Application site erythema Application site irritation Application site hypersensitivity Application site pruritus	

System Organ Class	Adverse Drug Reactions Frequency Category	
	Uncommon (≥1/1,000 to <1/100)	Not Known
	Application site pustules Application site reaction	
Immune System Disorders	Hypersensitivity	

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 and triazole derivatives. ATC Code: D01AC08.

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

Ketoconazole also has a direct anti-inflammatory action independent from its antifungal activity which may contribute to symptom relief in dandruff and seborrhoeic dermatitis.

5.2 Pharmacokinetic properties

Plasma concentrations of ketoconazole were not detectable after topical administration of Nizoral Shampoo 2% on the scalp. Plasma levels were detected after topical administration of Nizoral Shampoo 2% on the whole body.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies including acute oral and dermal toxicity, primary ocular irritation, repeat-dose dermal irritation and dermal toxicity. Ketoconazole has been shown to be teratogenic (syndactylia and oligodactylia) in the rat when given orally in the diet at 80 mg/kg/day; a dose that is 10 times above the maximum human oral dose on a mg/kg basis and more that 6000 times the plasma detection limit which was not reached in animal topical studies conducted by the Market Authorisation Holder.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium lauryl ether sulphate
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 (E127)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

1) High-density polyethylene bottle containing 60 ml, 100 ml or 120 ml Nizoral Dandruff Shampoo.

   Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel, Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/315/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26November 1999
Date of renewal of authorization: 26 November 2009

10 DATE OF REVISION OF THE TEXT

October 2019