

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nizoral 20mg/g Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of shampoo contains 20mg ketoconazole.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo

Product imported from the UK:

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, seborrhoeic dermatitis of the body or tinea (pityriasis) versicolor.

4.2 Posology and method of administration

Nizoral 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.

Tinea versicolor

Use once daily for up to 5 days.

For prophylaxis, use once daily for 3 days before prolonged exposure to the sun.

Method of administration

Cutaneous use.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Nizoral Shampoo, to prevent any potential rebound effect.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

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 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 ketoconazole 2% shampoo was evaluated in 2980 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 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 Application site pustules Application site reaction	
Immune System Disorders	Hypersensitivity	

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 performed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Imidazole and triazole derivatives.

ATC Code: D01AC08.

Ketoconazole is a synthetic imidazole dioxolane derivative with potent antifungal activity against dermatophytes, such as *Trichophyton* spp., *Epidermophyton* spp., *Microsporum* spp. and yeasts, such as *Candida* spp. and *Malassezia* spp. (*Pityrosporum* spp.).

5.2 Pharmacokinetic properties

Plasma concentrations of ketoconazole were not detectable after topical administration of Nizoral Shampoo on the scalp. Plasma levels were detected after topical administration of Nizoral Shampoo 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 than 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

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Overlabelled cardboard outer containing a 120ml bottle.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/93/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 17th April 2009

10 DATE OF REVISION OF THE TEXT

May 2014