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

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Nizoral Shampoo, to prevent any potential rebound effect.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

None known.

4.6 Fertility, pregnancy and lactation

There are no adequate and well controlled studies in pregnant or lactating women. To date, no other relevant epidemiological data are available. 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). No effects on the breastfed newborn/infant are anticipated. See Pharmacokinetic properties, section 5.2.

4.7 Effects on ability to drive and use machines

Not applicable.

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	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	

4.9 Overdose

In the event of accidental ingestion, only supportive 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

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 *Pityrosporum* ovale.

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 25ºC.

6.5 Nature and contents of container

High-density polyethylene bottle containing 120 ml shampoo

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

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1328/30/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 25th August 2006

Date of last renewal: 25th August 2011

10 DATE OF REVISION OF THE TEXT

August 2012