

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ketopine 20mg/g Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of shampoo contains 20 milligrams of Ketoconazole.
Each 1 ml of shampoo contains 20.84 milligrams of Ketoconazole.

Excipients:

Methyl benzoate	4.50 µg/g
Benzyl benzoate	0.30 µg/g
Benzyl Alcohol	5.00 mg/g
BHA	0.60 µg/g
BHT	0.30 µg/g
Ethanol	<0.03 µg/g
Propylene Glycol	<0.03 µg/g

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Shampoo.
Clear, pink, viscous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Ketoconazole 2% w/w shampoo is indicated in the treatment and prevention of seborrhoeic dermatitis of the scalp and pityriasis capitis in adults including the elderly and adolescents.

4.2 Posology and method of administration

For cutaneous administration.

For use in adults including the elderly and adolescents.

Water should be applied thoroughly to hair and scalp.
Sufficient shampoo (approx 5ml) to produce enough lather to wash the scalp and hair should be applied.
Shampoo should be gently massaged over the entire scalp and left for 3-5 minutes before rinsing thoroughly.

Use ketoconazole shampoo twice weekly for 2-4 weeks.

Prophylaxis
Use once a week or every other week to prevent the recurrence of symptoms.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Ketoconazole may be irritating to mucous membranes of the eyes and contact with this area should be avoided. If the shampoo does get into the eyes, they should be bathed gently with cold water.

In the event of long-term treatment with local corticosteroids, a rebound phenomenon can sometimes occur. To prevent this it is recommended to gradually discontinue use of the steroid, e.g. over 2-3 weeks, whilst simultaneously commencing treatment with ketoconazole shampoo.

Methyl benzoate and benzyl benzoate are mildly irritating to the skin, eyes and mucous membranes.

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 Shampoo 2% to the scalp of non-pregnant humans. Plasma levels were detected after topical administration of Ketoconazole Shampoo 2% on the whole body. There are no known risks associated with the use of Ketoconazole 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 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 from the available clinical trial data).

System Organ Class	Adverse Drug Reactions		
	Frequency Category		
	Uncommon	Rare	Not Known

	(≥1/1,000 to <1/100)	(≥1/10,000 to <1/1,000)	(cannot be estimated from the available clinical trial data)
Immune System Disorders		Hypersensitivity	
Nervous System Disorders		Dysgeusia	
Infections and Infestations	Folliculitis		
Eye Disorders	Increased lacrimation	Eye irritation	
Skin and Subcutaneous Tissue Disorders	Alopecia	Acne	Angioedema
	Dry Skin	Dermatitis contact	Urticaria
	Hair texture abnormal	Skin disorder	Hair colour changes
	Rash	Skin exfoliation	
	Skin burning sensation		
General Disorders and Administration Site Conditions	Application site erythema	Application site hypersensitivity	
	Application site irritation	Application site pustules	
	Application site pruritus		
	Application site reaction		

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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: <http://www.imb.ie/>; e-mail: imbpharmacovigilance@imb.ie

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: Antifungals for topical use; Imidazole and triazole derivatives, ATC Code: D01A C08

Ketoconazole is a synthetic imidazole-dioxalane derivative which inhibits the growth of fungi by altering the permeability of the cell membrane through inhibition of ergosterol biosynthesis. Ketoconazole has a wide spectrum of antimicrobial activity including activity against dermatophytes (*Trichophyton rubrum*, *T. mentagrophytes*, *T. tonsurans*, *Microsporum canis*, *M. audouini*, *M.*

gypseum and Epidermophyton floccosum) and yeasts (Candida albicans, C tropicalis, Pityrosporum ovale (Malassezia ovale) and Pityrosporum orbiculare (M. furfur)).

5.2 Pharmacokinetic properties

Percutaneous resorption of ketoconazole is negligible. No systemic absorption of ketoconazole has been demonstrated following either short or long treatment with shampoo containing ketoconazole.

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

Sodium Laureth Sulfate Paste 70 %
Disodium Laureth Sulfosuccinate Liquid 40%
Sodium Chloride
Citric Acid Monohydrate
Benzyl Alcohol
Tetrasodium EDTA
Quaternium-15
Polyquaternium-7
Dexpanthenol
Laureth-2
Sodium Hydroxide
Erythrosine (E127)
Perfume EBA 11175 (contains methyl benzoate, benzyl benzoate and benzyl alcohol)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

27 months.

6.4 Special precautions for storage

Do not store above 25 °C.

Store in original package.

Keep bottle tightly closed.

6.5 Nature and contents of container

White High-density polyethylene (HDPE) multi dose bottles with Polypropylene closures.

Pack sizes: 60 ml, 100 ml and 120 ml.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Limited
T/A Pinewood Healthcare
Ballymacarbry
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 281/125/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th September 2006

Date of last renewal: 20th February 2008

10 DATE OF REVISION OF THE TEXT

March 2014