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 with known effect
Benzyl Alcohol 5.00 mg/g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo.
Clear, pink to orange/red, 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

Posology

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.

Method of administration
For cutaneous administration

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.

This medicine contains 5.00 mg benzyl alcohol in each g which is equivalent to 0.50 % w/w. Benzyl alcohol may cause allergic reactions and mild local irritation.

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 (≥1/1,000 to <1/100)	Rare (≥1/10,000 to <1/1,000)	Not Known (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 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 HPRA Pharmacovigilance, Website: www.hpra.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
Imidazolidinyl Urea (Imidurea)
Polyquaternium-7
Dexpanthenol
Laureth-2
Sodium Hydroxide
Erythrosine (E127)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 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 Ltd
Ballymacarbry
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0281/125/001

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 2023