SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Ketoconazole 2% w/w Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each gram of shampoo contains 20 milligrams of Ketoconazole.
For a 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 for the treatment and prevention of seborrhoeic dermatitis, pityriasis capitis (dandruff) and pityriasis versicolor that may be associated with the fungus Pityrosporum.

4.2 Posology and method of administration
For topical administration.

Adults including the elderly and adolescents:
Wet hair and scalp thoroughly with water.
Apply sufficient shampoo to produce enough lather to wash the scalp and hair, gently massage it over the entire scalp and leave for 3-5 minutes before rinsing thoroughly.

Seborrhoeic dermatitis and dandruff: Use Ketoconazole 2% w/w shampoo twice weekly for 2-4 weeks.

Prophylaxis: Use Ketoconazole 2% w/w shampoo once every 1-2 weeks.

Pityriasis versicolor: Use Ketoconazole 2% w/w shampoo once daily for a maximum of 5 days.
Prophylaxis: As patches of pityriasis versicolor become more apparent on exposure to the sun. Ketoconazole 2% w/w shampoo may be used once daily for a maximum of 3 days in a single treatment course before exposure to sunshine.

4.3 **Contraindications**
Hypersensitivity to ketoconazole or any of the excipients.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 – 3 weeks, while using Ketoconazole 2% w/w shampoo, to prevent any potential rebound effect.

Ketoconazole 2% w/w shampoo may be irritating to mucous membranes of the eyes and contact with this area should be avoided. If Ketoconazole 2% w/w shampoo does get into the eyes, they should be bathed gently with cold 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**
Ketoconazole 2% w/w shampoo is not detected in plasma after chronic shampooing or topical application.

Ketoconazole 2% w/w shampoo is not contraindicated for pregnancy or lactation, but caution should be exercised.

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 $\geq 1\%$.

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 and < 1/10

Uncommon ≥ 1/1,000 and <1/100

Rare ≥ 1/10,000, <1/1,000

Very rare <1/10,000, including isolated reports

Not known (cannot estimate from the available clinical trial data).

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<th>System Organ Class</th>
<th>Adverse Drug Reactions</th>
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<td>Frequency Category</td>
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<td>Uncommon</td>
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<td>Rare</td>
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<td>Not Known</td>
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<td>Application site pruritus</td>
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<td>Application site reaction</td>
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**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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.
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 (ATC) Classification: D01A C08*
Ketoconazole is a synthetic imidazole-dioxalane derivative. It is a broad spectrum antifungal agent which inhibits the growth of common dermatophytes and yeasts by altering the permeability of the cell membrane:
- **Dermatophytes:** *Trichophyton rubrum, T. mentagrophytes, T.tonsurans, Microsporum canis, M. audouini, M. gypseum* and *Epidermophyton floccosum.*
- **Yeasts:** *Candida albicans, C tropicalis, Pityrosporum ovale (Malassezia ovale)* and *Pityrosporum orbiculare (M. furfur).*

5.2 Pharmacokinetic properties
Ketoconazole was not detected in plasma in 39 patients who shampooed 4-10 times per week for 6 months or in patients who shampooed 2-3 times per week for 3-26 months. Twelve hours after a single shampoo, hair samples taken from six patients showed that high amounts of ketoconazole were present on the hair; only about 5% had penetrated into the hair keratin. There were no detectable plasma levels after chronic shampooing twice weekly for two months with ketoconazole.

5.3 Preclinical safety data
There is no relevant information additional to that contained elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
- Sodium Laureth Sulfate Paste 70%
- Disodium Laureth Sulfo succinate Liquid 40%
- Sodium Chloride
- Citric Acid Monohydrate
- Benzyl Alcohol
- Tetrasodium EDTA
- Quaternium-15
- Polyquaternium-7
Dexpanthenol
Laureth-2
Sodium Hydroxide
Erythrosine (E127)
Perfume
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 container.
Keep container tightly closed

6.5 Nature and contents of container
White High-density polyethylene (HDPE) multi dose bottles with
Polypropylene flip top closures.

Pack sizes: 120 ml.

6.6 Special precautions for disposal
Not applicable.

7 MARKETING AUTHORISATION HOLDER
Pinewood Laboratories Limited trading as Pinewood Healthcare
Ballymacarbry,
Clonmel,
Co. Tipperary,
Ireland

8 MARKETING AUTHORISATION NUMBER(S)
PL 00327/0178
9  DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10  DATE OF REVISION OF THE TEXT