

1 NAME OF THE MEDICINAL PRODUCT

Ketopine Dandruff Shampoo
Boots Anti-Dandruff Ketoconazole 2% w/w Shampoo
Ketoconazole 20 mg/g Anti-Dandruff Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of shampoo contains 20 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

Ketopine Dandruff Shampoo is indicated for the prevention and treatment of dandruff.

4.2 Posology and method of administration

For topical administration.

Do not use shampoo more often than directed.

Ketopine Dandruff Shampoo is for use in adults including the elderly and adolescents:

Wet hair and scalp thoroughly with water.

Apply sufficient shampoo to wash the scalp and hair and lather well.

Gently massage it over the entire scalp and leave for 3-5 minutes before rinsing thoroughly.

Use shampoo every 3-4 days for 2-4 weeks. There should be a minimum of 3 days between applications.

Prophylaxis: Use shampoo once every 1-2 weeks

4.3 Contraindications

Hypersensitivity to ketoconazole or any of the excipients

4.4 Special warnings and precautions for use

Ketopine Dandruff Shampoo 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.

Long-term treatment with steroids. Stopping prolonged treatment with steroids requires the gradual reduction of application of the steroid over a period of 2-3 weeks while simultaneously using ketoconazole. This is to prevent the condition flaring up.

If the scalp is not cleared within 4 weeks of treatment a doctor or pharmacist should be consulted.

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.

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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.

This medicine contains 156.00 mg sodium laurilsulfate in each g which is equivalent to 15.60 % w/w. Sodium laurilsulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

4.6 Fertility, pregnancy and lactation

Ketoconazole is not detected in plasma after chronic shampooing or topical application.

Ketopine Dandruff Shampoo is not contraindicated for pregnancy or lactation, but caution should be exercised.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The safety of Ketopine Shampoo was evaluated in 2980 subjects who participated in 22 clinical trials. Ketopine 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 Ketopine Dandruff Shampoo from either clinical trial or postmarketing experiences. The displayed frequency categories use the following convention:

Very common ($\geq 1/10$); common ($\geq 1/100$ to $<1/10$); uncommon ($\geq 1/1,000$ to $<1/100$); rare ($\geq 1/10,000$ to $<1/1,000$); very rare ($<1/10,000$); and not known (cannot be estimated from the available clinical trial data).

Table 1: Adverse Drug Reactions

| System Organ Class | Adverse Drug Reactions | | |
|---|--|--|---------------------|
| | Frequency Category | | |
| | Uncommon ($\geq 1/1,000$ to $<1/100$) | Rare ($\geq 1/10,000$ and $<1/1,000$) | Not known |
| 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 | Application site erythema | Application site | |

| | | | |
|---------------------------------------|---|---|--|
| Administration Site conditions | Application site irritation Application site pruritus Application site reaction | 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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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*).

Ketoconazole also has a direct anti-inflammatory action independent from its antifungal activity which may contribute to symptom relief in dandruff and seborrhoeic dermatitis.

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 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 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: 60 ml, 100 ml
All pack sizes may not be marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Limited
Ballymacarbry
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 04917/0063

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10.10.2003 / 26.03.2009

10 DATE OF REVISION OF THE TEXT

06/10/2025