

1. NAME OF THE MEDICINAL PRODUCT

Ketofung® (Ketoconazole 2%) Shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoconazole2% w/w

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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)
- pityriasis versicolor that may be associated with the fungus *Pityrosporum*.

4.2 Posology and method of administration

Posology

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 Ketofung® shampoo twice weekly for 2-4 weeks.

Prophylaxis: Use Ketofung® shampoo once every 1-2 weeks

Pityriasis versicolor: Use Ketofung® shampoo once daily for a maximum of 5 days.

Prophylaxis: As patches of pityriasis versicolor become more apparent on exposure to the sun.

Ketofung® 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

For patients undergoing prolonged treatment with topical corticosteroids, it is advisable to gradually

discontinue the steroid therapy over a period of 2 – 3 weeks. During this tapering process, it is recommended to use Ketoconazole 2% w/w shampoo concurrently to prevent any potential rebound effect. Please be cautious when using Ketoconazole 2% w/w shampoo near the eyes, as it may cause irritation to the mucous membranes. Avoid direct contact with the eye area, and in case of accidental contact, gently cleanse the eyes with cold water.

Keep out of reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed

4.6 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 $\geq 1/10$

Common $\geq 1/100$ and $< 1/10$

Uncommon $\geq 1/1,000$ and $< 1/100$

Rare $\geq 1/10,000$, $< 1/1,000$

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

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

System Organ Class	Adverse Drug Reactions		
	Frequency Category		
	Uncommon ($\geq 1/1,000$ and $< 1/100$)	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	Alopecia	Acne	Angioedema

Disorders	Dry Skin Hair texture abnormal Rash Skin burning sensation	Dermatitis contact Skin disorder Skin exfoliation	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	

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: Imidazole antifungal.

ATC code: D01AC08

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*).

Mechanism of action

Ketoconazole interacts with 14- α -sterol demethylase, a cytochrome P-450 enzyme necessary for the conversion of lanosterol to ergosterol. This results in inhibition of ergosterol synthesis and increased fungal cellular permeability due to reduced amounts of ergosterol present in the fungal cell membrane. This metabolic inhibition also results in accumulation of 14 α -methyl-3,6-diol, a toxic metabolite. The increase in membrane fluidity is also thought to produce impairment of membrane-bound enzyme systems as components become less closely packed.

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

Guar Hydroxypropyltrimonium Chloride
Cocamidopropyl Betaine (Dehyton PK 45)
Sodium Laureth Sulphate (Texapon N70)
Cocamide DEA (Comperlan COD)
Coco-Glucoside and Glycerylolate (Lamesoft PO 65)
Lemon Grass Fragrance
Butylated HydroxyAnisole
Erythosine Lake
Sodium Chloride
Disodium EDTA
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C in tight container protected from light and moisture. Keep this medicine of sight and reach of children.

6.5 Nature and contents of container and special equipment for use, administration or implantation

White High-density polyethylene (HDPE) multi dose bottles with Polypropylene flip top closures.
Pack sizes: 60ml and 100 ml

6.6 Special precautions for disposal and other handling

Not applicable.

7. APPLICANT/MANUFACTURER

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