

SUMMARY PRODUCT CHARACTERISTIC (SPC)

KETOCONAZOLE 2 % Shampoo

1. NAME OF THE MEDICINAL PRODUCT

Ketoconazole

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of shampoo contains:

active ingredient: ketoconazole – 20mg;

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Shampoo

A viscous red liquid with a pleasant apple aroma.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Ketoconazole, 2% shampoo is used for the treatment of fungal infections, pityriasis versicolor and conditions like seborrheic dermatitis and dandruff. Shampoo controls flaking, scaling and itching, associated with dandruff.

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% shampoo twice weekly for 2-4 weeks.

Prophylaxis: Use Ketoconazole, 2% shampoo once every 1-2 weeks

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 – 3 weeks, while using Ketoconazole, 2% shampoo, to prevent any potential rebound effect.

Ketoconazole, 2% shampoo may be irritating to mucous membranes of the eyes and contact with this area should be avoided. If Ketoconazole 2% 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. Pregnancy and lactation

Ketoconazole, 2% shampoo is not detected in plasma after chronic shampooing or topical application.

Ketoconazole, 2% 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).

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 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	Application site hypersensitivity Application site pustules	

	pruritus Application site reaction		
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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 online to the "Center of Drug and Medical Technologies Expertise" SNPO of MoH of RA via www.pharm.am or call the hotline numbers: (+374 10) 20 05 05 and (+374 96) 22 05 05.

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: D01AC08

Pharmacotherapeutic group: Dermatologicals, antifungals for dermatologicals use, antifungals for topical use, Imidazole and triazole derivatives, ketoconazole.

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. audouinii*, *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.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Cocamide DEA

Cocamidopropyl betaine

Sodium laureth sulfate

Diazolidinyl urea

Hydrochloric acid (conc)

Triethanolamine 98 %

Sodium chloride

Flavor apple

Color red E-129

Water deionized

6.2. Incompatibilities

Not applicable.

6.3. Shelf Life

3 years.

6.4. Special precautions for storage

Store at a temperature not higher than 25°C, in a dry place, out of the reach of children. Protect from light.

6.5. Nature and contents of container

2% shampoo, 90 ml in a plastic bottle (inside package)

The 1 bottle with leaflet packed in cardboard box (outer package)

6.6. Special precautions for disposal

Not applicable

7. MARKETING AUTHORIZATION HOLDER

“ARPIMED” LLC

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8. MARKETING AUTHORISATION NUMBER**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

26.02.2004

10. DATE OF REVISION OF THE TEXT