



National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS

KERATIN BLUZ SHAMPOO

(Ketoconazole 2% Shampoo)

1. NAME OF THE MEDICINAL PRODUCT

Ketoconazole 2% Shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Ketoconazole USP 2% w/w

Zinc Pyrithione[ZPTO]..... 1% w/w

In a Conditioning Baseq.s

Colour : Approved Colours used

3. PHARMACEUTICAL FORM

Shampoo

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:

Moisten the hair and scalp thoroughly with water. Apply sufficient lotion to produce enough lather to wash scalp and hair and gently massage it over the entire scalp area for about 1 minute. Rinse hair thoroughly with water.

Repeat the procedure leaving the lotion on scalp for 3minutes. After the second thorough rinse, dry hair with towel or warm air flow. Use twice a week for 4 weeks with at least 3 days between each application and then intermittently as needed to maintain control or use as directed by physician.

The infected parts of the skin should be washed with Ketoconazole Shampoo 2%, allowing the product to soak in for 3 to 5 minutes before rinsing. The skin itself should be thoroughly washed, not just the hair.

4.3 Contraindication:

Hypersensitivity to ketoconazole or any of the excipients.

4.4 Special warnings and precautions for use

FOR EXTERNAL USE ONLY

In patients who have been on prolonged treatment with topical corticosteroids, it is

recommended that the steroid therapy be gradually withdrawn over the period of 2 to 3 weeks, while using Ketoconazole Shampoo 2%, to prevent any potential rebound effect. Avoid contact with the eyes. If the shampoo gets into the eyes, wash the eyes with copious amount of 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 General principles

There are no adequate and well-controlled studies in pregnant or lactating women. Plasma concentrations of ketoconazole were not detectable after topical administration of Ketoconazole Shampoo 2% to the scalp of non-pregnant humans.

There are no known risks associated with the use of Ketoconazole Shampoo 2% in pregnancy or lactation.

Adults, Elderly and Children:

Use the shampoo twice weekly for 2-4 weeks. Wash affected areas of skin (not just the hair), using a palm full of shampoo and leave for 3-5 minutes before rinsing..

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

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 ($\geq 1/1,000$ & $< 1/100$)	Rare ($\geq 1/10,000$ & $< 1/1,000$)	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 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:

Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antifungal activity against dermatophytes, such as *Trichophyton* spp., *Epidermophyton* spp., *Microsporum* spp., and yeasts, such as *Candida* spp. and *Malassezia* spp. (*Pityrosporum* spp.).

Zinc pyrithione is best known for its use in treating dandruff and seborrhoeic dermatitis. It has fungistatic (that is, it inhibits the division of fungal cells) and bacteriostatic (inhibits bacterial cell division) properties and is used in the treatment of seborrhoeic dermatitis. It is effective against many pathogens from the *Streptococcus* and *Staphylococcus* genera. Ketoconazole

Shampoo 2% rapidly relieves scaling and pruritus, which are usually associated with seborrhoeic dermatitis, pityriasis capitis (dandruff) and pityriasis versicolor.

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:

Salicylic acid(BP)

Sodium Lauryl Ether Sulphate(IHS)

Coco Diethanolamine(IHS)

Coco Amido Propyl Batiene(IHS)

2,Phenoxy Ethanol(BP)

Sodium Methyl Paraben(Sodium Methyl Hydroxy Benzoate) (BP)

Sodium Propyl Paraben(Sodium Propyl Hydroxy Benzoate) (BP)

Disodium Edetate(BP)

Propylene Glycol(BP)

Citric acid(BP)

Perfume West(Gogia) (IHS)

6.2 Incompatibilities: NONE

6.3 Shelf life:

30 months

6.4 Special precautions for storage:

Store in original container.

Keep container tightly closed.

6.5 Nature and contents of container:

Pack sizes: 150 ml.

6.6 Special precautions for disposal and other handling:

Not applicable.

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

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