

**MICRO LABS LIMITED, INDIA**

**SUMMARY OF PRODUCT CHARACTERISTICS**

**PRODUCTNAME: KETOCONAZOLE SHAMPOO 2% w/v**

**BRAND NAME: PHYTORAL SHAMPOO**



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**SUMMARY OF PRODUCT CHARACTERISTICS**

**1. NAME OF THE MEDICINAL PRODUCT**

**1.1 Product Name:**

Ketoconazole Shampoo

Phytoral Shampoo

**1.2 Strength:**

2% w/v

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Ketoconazole USP .....2.0% w/v

**3. PHARMACEUTICAL FORM**

Shampoo for Topical use

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Prevention and treatment of infections in which the yeast *Malassezia* (previously called *Pityrosporum*) is likely to be involved, such as dandruff and seborrhoeic dermatitis. Treatment of tinea (pityriasis) versicolor.

**4.2 Posology and method of administration**

For topical administration.

Ketoconazole shampoo 2% is for use in adolescents and adults;

Wash affected areas and leave for 3-5 minutes before rinsing. Usually, a palmful of shampoo suffices for one wash.

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Dandruff and seborrhoeic dermatitis:	Wash hair twice weekly for 2-4 weeks.
Tinea versicolor:	Once daily for 1-5 days.

Prophylaxis:

Dandruff and seborrhoeic dermatitis:	Use once every 1-2 weeks.
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Paediatric population

The safe and effective use of Ketoconazole 2% shampoo in infants and children under the age of 12 years has not been established.

**4.3 Contraindications**

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 to 3 weeks, while using Ketoconazole 2% shampoo, to prevent any potential rebound effect.

Keep out of the eyes. If the shampoo should get into the eyes, they should be bathed with water.

**4.5 Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed

**4.6 Pregnancy and lactation**

There are no adequate and well-controlled studies in pregnant or lactating women. Data on a limited number of exposed pregnancies indicate no adverse effects of topical ketoconazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of ketoconazole. No effects on the breastfed newborn/infant are anticipated.

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Plasma concentrations of ketoconazole were not detectable after topical administration of Ketoconazole Shampoo 2% to the scalp of non-pregnant humans. Plasma levels were detected after topical administration of Ketoconazole Shampoo 2% on the whole body. There are no known risks associated with the use of Ketoconazole Shampoo 2% in pregnancy or lactation

**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 2890 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 post marketing 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 ( $< 1/10,000$ )

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

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

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<b>Immune System disorders</b>		Hypersensitivity	
<b>Nervous System Disorders</b>		Dysgeusia	
<b>Infections and Infestations</b>	Folliculitis		
<b>Eye Disorders</b>	Increased lacrimation	Eye irritation	
<b>Skin and Subcutaneous Tissue Disorders</b>	Alopecia Dry skin Hair texture abnormal Rash Skin burning sensation	Acne Dermatitis contact Skin disorder Skin exfoliation	Angioedema Urticaria Hair colour changes
<b>General Disorders and Administration Site Conditions</b>	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 (ATC) Classification: 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:

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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**

Plasma concentrations of ketoconazole were not detectable after topical administration of Ketoconazole 2% shampoo on the scalp. Plasma levels were detected after topical administration of Ketoconazole 2% shampoo on the whole body.

### **5.3 Preclinical safety data**

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

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**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Propylene glycol

Sodium Lauryl Sulphate

Cresmer SB

Erythrosine Color Supra

Freshna S1072

Swiss bonquet P3043

Forestall

**6.2 Incompatibilities**

Not Applicable

**6.3 Shelf life**

The Shelf life is 18 months from the date of manufacture

**6.4 Special precautions for storage**

Do not store above 30°C

**6.5 Nature and contents of container**

HDPE bottle of 100 ml

**6.6 Special precautions for disposal and other handling**

No Special requirement

**7. Marketing Authorization Holder:**

MICRO LABS LIMITED

31, Race Course Road

Bangalore-560001

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**8. Marketing Authorization Numbers**

Rwanda FDA-HMP-MA-0042

**9. Date of first authorization**

18th January 2021

**10. Date of revision of the text**

July 2021