

# Summary of Product Characteristics

## 1. NAME OF THE MEDICINAL PRODUCT

Conaz Skin & Scalp Application

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Ketoconazole ..... 20mg

For the full list of excipients, see section 6.1 of SPC below

## 3. PHARMACEUTICAL FORM

Reddish pink to reddish orange colored, slightly viscous lotion having lemon odor.

## 4. CLINICAL PARTICULARS

Conaz Skin and Scalp Application is indicated for the treatment and prophylaxis of dermal infections caused by *Pityrosporum Ovale* or *Malassezia furfur*, as well as it is also indicated in *Candida*

### 4.1. Therapeutic indications

*albicans* infections.

It is useful in:

- Seborrhoeic dermatitis.
- Flaking, scaling and itching associated with dandruff (*Pityriasis Capitis*).
- *Pityriasis versicolor* / *Tinea versicolor*.

It may also be used for other fungal infections of the skin as determined by doctor.

### 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% w/w shampoo twice weekly for 2-4 weeks.

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

**Pityriasis versicolor:** Use Ketoconazole 2% w/w 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% w/w 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 other excipients of this product.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 – 3 weeks, while using Ketoconazole 2% w/w shampoo, to prevent any potential rebound effect.

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Ketoconazole 2% w/w shampoo may be irritating to mucous membranes of the eyes and contact with this area should be avoided. If Ketoconazole 2% w/w 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. Fertility, 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**

None, since Ketoconazole is absorbed through the sk

#### **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 post marketing 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<br>( $\geq 1/1,000$ and $< 1/100$ )                                    | Rare<br>( $\geq 1/10,000$ 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<br>Dry Skin<br>Hair texture abnormal<br>Rash<br>Skin burning sensation | Acne<br>Dermatitis contact<br>Skin disorder<br>Skin exfoliation | Angioedema<br>Urticaria<br>Hair colour changes |
| General Disorders and                  | Application site                                                                | Application site                                                |                                                |

|                                |                                                                                                   |                                               |  |
|--------------------------------|---------------------------------------------------------------------------------------------------|-----------------------------------------------|--|
| Administration Site Conditions | erythema<br>Application site irritation<br>Application site pruritus<br>Application site reaction | hypersensitivity<br>Application site pustules |  |
|--------------------------------|---------------------------------------------------------------------------------------------------|-----------------------------------------------|--|

#### Reporting of suspected adverse reactions

*Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Agency.*

### 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 and triazole derivatives (antifungals)

**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*).

### 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

Coconut Diethanolamide  
Disodium Edetate  
Erythrosine Red 3  
Glycerol  
Methyl Paraben  
Oil of Lemon Excellent EF  
Phenyl Ethyl Alcohol

Propylene Glycol  
Sodium Lauryl Ether Sulphate  
Polyquarternium 44  
Cocamidopropyl Betaine 30%  
Sodium Chloride  
Citric Acid Monohydrate  
Purified Water

**6.2. Incompatibilities**

Not applicable.

**6.3. Shelf life**

02 Years

**6.4. Special precautions for storage**

Do not store & transport above 30°C and avoid freezing.  
Protect from light & heat.

**6.5. Nature and contents of the container**

100ml in plastic bottle, packed in a printed carton.

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

Not applicable

**7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS**

ATCO Laboratories Limited  
B-18, S.I.T.E., Karachi – 75700  
Pakistan.

**8. MARKETING AUTHORISATION NUMBER**

16040

**9. DATE OF FIRST AUTHORISATION**

**10. 25/07/2026**

**11. DATE OF REVISION OF THE TEXT**

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