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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 – 3 weeks, while using Ketoconazole 2% w/w shampoo, to prevent any potential rebound effect.

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 ≥ 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 ≥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 (≥1/1,000 and <1/100)	Rare (≥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	Application site	Application site	

Administration Site Conditions	erythema Application site irritation Application site pruritus Application site reaction	hypersensitivity 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