SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

CANCAN (Ketoconazole Shampoo 2 % w/v)

2. Qualitative and quantitative composition

Composition

Ketoconazole USP 2.0 % w/v

Shampoo Base q.s

Colour:Ponceau 4R

For a full list of excipients, see Section 6.1.

3. Pharmaceutical form

Shampoo
A red colored clear Shampoo

4. Clinical particulars

4.1 Therapeutic indications

CANCAN (Ketoconazole Shampoo 2 % w/v) 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

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 **CANCAN** shampoo twice weekly for 2-4 weeks.
Prophylaxis: Use **CANCAN** shampoo once every 1-2 weeks
Pityriasis versicolor: Use **CANCAN** 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 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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over a period of 2 – 3 weeks, while using CANCAN shampoo, to prevent any potential rebound effect.

CANCAN 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.

This medicine contains 5.00 mg benzyl alcohol in each g which is equivalent to 0.50 % w/w. Benzyl alcohol may cause allergic reactions and mild local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed

4.6 Fertility, pregnancy and lactation

CANCAN shampoo is not detected in plasma after chronic shampooing or topical application.
CANCAN 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 CANCAN 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 CANCAN 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 Administration Site Conditions	Application site erythema Application site irritation Application site pruritus Application site reaction	Application site hypersensitivity Application site pustules	

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 via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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: D01A C08

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

Sr. No.	Raw Material	Pharmacopoeia
1.	Sulfocare SB-25/C	IHS
2.	Imidurea	USP
3.	Sulfuric Acid	BP
4.	Colour Ponceau 4R Supra	IHS
5.	Sodium Hydroxide Pellets	BP
6.	Fragrance AL012403	IHS
7.	Purified Water	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30^0 C in dry and dark place. Do not freeze.

6.5 Nature and contents of container

100 ml PET Bottle

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing Authorisation Holder

Kilitch Drugs (India) Limited
37, Ujagar Industrial Estate,
W.T Patil Marg, Deonar,
Mumbai 400 088,Maharashtra, India.
Website- www.kilitch.com

8. Marketing Authorisation Number (S) issued by Ethiopian FDA

07847/07579/VAR/2021

9. Date of First Authorisation/Renewal of the Authorisation

30-09-2022

10. Date of Revision of the Text

04/07/2023