

Summary of product characteristics

1. Name of the medicinal product

KTC Shampoo (Ketoconazole & Zinc Pyrithione)

2. Qualitative and quantitative composition

Ketoconazole 2.0% w/v and Zinc Pyrithione 1.0% w/v

No any excipients of known effect.

3. Pharmaceutical form

Shampoo for topical application

4. Clinical particulars

4.1 Therapeutic indications

Treatment and prophylaxis of infections in which the yeast *Malassezia* (previously called *Pityrosporum*) is involved, such as pityriasis versicolor (localised), seb-orrhoeic dermatitis and pityriasis capitis (dandruff).

4.2 Directions for Use and Dosage

For topical administration.

The affected areas of the skin or the scalp should be washed with KTC shampoo 2%, which should be left on the skin/scalp for 3 to 5 minutes before rinsing.

Treatment:

- Pityriasis versicolor: once daily for 5 days.
- Seborrhoeic dermatitis and pityriasis capitis: twice weekly for 2 to 4 weeks.

Prophylaxis: -

-Pityriasis versicolor: once daily for 3 days during a single treatment course before the summer.

-Seborrhoeic dermatitis and pityriasis capitis: once every 1 or 2 weeks

4.3 Contraindications

KTC Shampoo 2% is contraindicated in individuals with unknown hypersensitivity to any of its ingredients.

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have been on prolonged treatment with topical corticosteroids, it is recommended that the steroid therapy be gradually withdrawn over the period of 2 to 3 weeks, while using KTC Shampoo 2%, to prevent any potential rebound effect.

Avoid contact with 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

None known.

4.6 Fertility, pregnancy and lactation

There are no adequate and well-controlled studies in pregnant or lactating women.

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

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

Eye irritation, Increased lacrimation, Hypersensitivity, Folliculitis, Dysgeusia, Acne, Alopecia, Dry skin, Hair texture abnormal, Skin burning sensation, Rash, Skin disorder, Skin exfoliation.

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 pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS)

<https://pv.pharmacyboardkenya.org>.

4.9 Overdose

In the event of accidental ingestion, supportive and symptomatic measures should be carried out. To avoid aspiration, emesis or gastric lavage should be performed.

5. Pharmacological properties

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

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical particulars

6.1 List of Excipients

Citric Acid Anhydrous
Disodium EDTA
Glycerin
Sodium Hydroxide Pellets
Sodium Methyl Paraben
Crismophar
Galaxy (SLS) Liquid
Col. Erythrosine Supra
Galaxy Pearly Shampoo base
Aloe vera Powder
Fla. Kashmir
Coco amino propyl betain
Dimethycon 1
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precaution for storage

Do not store above 30°C.

6.5 Nature and contents of container

100 ml white HDPE bottle with polypropylene (PP) cap and measuring cup packed in a carton along with pack insert.

6.6 Special precautions for disposal

Not applicable

7. Marketing Authorization Holder

Surgilinks building,
Apposite of James Mombasa Road, Nairobi
P.O Box 38936-00623
Nairobi, Kenya

Manufacturing address

Yash pharma laboratories pvt ltd
Khasra no. 19m, village raipur, pargana, bhagwanpur, tehsil, roorke, dist:
haridwar, uttarakhand, 247667, india

8. Marketing Authorisation Number(s):

H2024/CTD8430/16931

9. Date of First Authorisation/Renewal of the Authorisation

Date of First Authorisation:09/02/2024.

10. Date of revision of the text

November 2024