

SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product:

- 1.1 Product Name**
Ketovid Cream 2% w/w
- 1.2 Strength**
Each 100 g contains:
Ketoconazole 2g
- 1.3 Pharmaceutical Dosage Form**
Topical

2-Quality and Quantitative Composition:

ACTIVE INGREDIENT	Per100g
Ketoconazole	2g

3-Pharmaceutical Form:

White to off white, opaque cream.

4-Clinical Particulars

- 4.1 Therapeutic indications**
Treatment of dermatophyte infections of the skin-tinea corporis, tinea cruris, tinea manus and tinea pedis caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Microsporum canis* and *Epidermophyton floccosum* as well as in the treatment of cutaneous candidiasis, pityriasis versicolor and seborrheic dermatitis.
- 4.2 Posology and method of administration**
Topical.
Cutaneous candidiasis, tinea corporis, tinea cruris, tinea manus, tinea pedis or tinea (pityriasis) versicolor: Apply to the affected skin and immediate surrounding areas, once a day.

Seborrheic dermatitis: Apply to the affected skin or areas, once or twice a day depending on the severity of infection.

Treatment should be continued for a sufficient period, at least until a few days after disappearance of all symptoms. The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks of treatment. General measures in regard to hygiene should be observed to control sources of infection or reinfection.

The usual duration of treatment is: tinea versicolor 2-3 weeks, yeast infections 2-3 weeks, tinea cruris 2-4 weeks, tinea corporis 3-4 weeks, tinea pedis 4-6 weeks. The usual duration of treatment for seborrheic dermatitis is 2 to 4

wees. Maintenance therapy is applied once or twice weekly in seborrheic dermatitis.

4.3 Contraindications

Ketoconazole cream is contraindicated in individuals who have shown hypersensitivity to ketoconazole and any of its ingredients.

4.4 Special warning and precautions for use

Ketovid cream is not for ophthalmic use. Irritation may occur when ketoconazole cream is used immediately after prolonged treatment with topical corticosteroids. Therefore, it is recommended to continue applying the topical corticosteroid in the mornings and to apply ketoconazole cream in the evenings, and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks. In case a potent steroid is used, replace it by a mild steroid and withdraw therapy over the same period.

4.5 Interaction with other medicinal products

No known drug interaction since Ketovid Cream applied topically is not absorbed.

4.6 Pregnancy and lactation

Not relevant since Ketovid Cream applied topically is not absorbed.

4.7 Effects on ability to drive and use machine

Not known.

4.8 Undesirable effects

A few instances of irritation and burning sensation have been observed during treatment with ketoconazole cream. In rare circumstances allergic local skin phenomena, such as contact dermatitis, have been associated with ketoconazole cream or its components like propylene glycol.

4.9 Overdose

Exaggerated topical application may lead to erythema, oedema and burning sensation, which will disappear upon discontinuation of the treatment.

Treatment for overdose: No special measures have to be taken in case of accidental ingestion.

5-Pharmacological Properties :

5.1 Pharmacodynamic properties

Ketoconazole is a synthetic imidazole dioxolane derivative which has a potent antimycotic activity against dermatophytes such as *Trichophyton sp.*, *Epidermophyton floccosum* and *Microsporum sp.* and against yeasts. The effect on *Pityrosporum sp.* is very pronounced. Ketoconazole cream usually acts very rapidly on pruritis which is commonly seen in dermatophyte and yeast infections as well as skin conditions related with the presence of *Pityrosporum sp.* This symptomatic improvement is observed before the first signs of healing are observed.

5.2 Pharmacokinetic properties

Ketovid cream does not produce detectable blood levels after topical application.

6-Pharmaceutical Particulars:

6.1 List of excipients

Triethanolamine
Polysorbate 80
Polysorbate 60
Cetyl Alcohol
Stearyl Alcohol
Liquid Paraffin
Propylene Glycol
Disodium EDTA
Sorbitan Monooleate
Butylated Hydroxytoluene
Purified Water

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

Proposed 3 years

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

Descriptions of each packaging material for Ketovid Cream 2% w/wis as below:

Immediate Container/Packaging

Collapsible Aluminium Tube

Material of construction

Body : 99.7% aluminium purity
Internal lacquered : Epoxy phenolic
External lacquered : Polyester enamel
Cap : High density polyethylene

Description

Cap : White screw cap
Finishing (Body) : Internally lacquered, external preprinted and fitted with caps as per approved design.

Secondary Packaging Components

Outer Container/Packaging

Type: Unit box

Material: Paper carton

6.6 Special precautions for disposal

Not Applicable

7-Marketing Authorization Holder & Manufacturer Name:

Name : HOVID Bhd.
Address : 121, Jalan Tunku Abdul Rahman,
(Jalan Kuala Kangsar)
30010 Ipoh, Perak, Malaysia

8-Date of revision of the text :

April 2023

9-Instruction for preparation of Radiopharmaceuticals (If applicable):

Not Applicable