

SUMMARY OF PRODUCT CHARACTERISTICS



1. NAME OF THE FINISHED PHARMACAEUTICALS PRODUCT

Dezor Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoconazole 2% w/w

3. PHARMACEUTICAL FORM

White cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Topical treatment of tinea corporis, tinea cruris, tinea pedis, pityriasis versicolor and cutaneous candidiasis.

4.2 Posology and method of administration

Apply once daily. Duration of treatment: Pityriasis versicolor, yeast infection, tinea cruris, tinea corporis 2 weeks and tinea pedis 4-6 weeks.

4.3 Contraindications

Ketoconazole Cream is contra-indicated in individuals who have shown hypersensitivity to any of its ingredients. Ketoconazole Cream is not for ophthalmic use.

4.4 Special warning and precautions for use

If irritation or sensitivity occurs, treatment should be discontinued. Do not use on children under 2 years of age except under the advice and supervision of a doctor. Avoid contact with eyes and mucous membranes (for external use only). Consult doctor if there is no improvement in 4 weeks (for athlete's foot) or 2 weeks (for jock itch). Overgrowth of non-susceptible organisms may occur with prolonged use of any topical antimicrobial agent including Ketoconazole.

4.5 Interaction with other medicinal products and other forms of interactions

Concomitant administration of Ketoconazole with rifampicin results in decreased antifungal activity. Concurrent use of Ketoconazole and Phenytoin may alter serum concentrations of both drugs.

4.6 Pregnancy and lactation

Animal studies and studies in human volunteers have failed to demonstrate absorption of Ketoconazole Cream, however due to the teratogenic nature of the active ingredient, Ketoconazole Cream should only be used in pregnant or lactating woman if in the judgement of the treating physician, the expected benefits outweigh potential risk.

4.7 Effects on ability to drive and use machine

Unknown.

4.8 Undesirable effects

Signs of skin irritation-burning sensation, pruritus, dermatitis were observed in 3.0% of Ketoconazole treated patients and in 2.0% of placebo controls during clinical trials.

4.9 Overdose

No known information available concerning overdosage in human.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Ketoconazole is an imidazole antifungal agent which interferes with ergosterol synthesis and therefore alters the permeability of the cell membrane of sensitive fungi.

5.2 Pharmacokinetic Properties

Ketoconazole is a broad-spectrum synthetic antifungal agent which inhibits the growth of the following 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* and *C. tropicalis* and the organism responsible for tinea versicolor, *Malassezia furfur* (*Pityrosporum orbiculare*). Development of resistance to Ketoconazole has not been established. *In vitro* studies suggest that Ketoconazole impairs the synthesis of ergosterol which is a vital component of fungal cell membranes. The mechanism of therapeutic effect of Ketoconazole in seborrheic dermatitis has not been established.

5.3 Preclinical Safety Data

Not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylated hydroxytoluene, Chlorocresol, Hydrochloric Acid 37%, Dibasic Sodium Phosphate, Polyethylene Glycol 400, White Soft Paraffin, Liquid Paraffin, Cetomacrogol Emulsifying Wax and Purified Water.

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of container

15g aluminium tube

7. MARKETING AUTHORIZATION HOLDER

HOE Pharmaceuticals Sdn. Bhd.,

Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman, 42000 Port Klang, Selangor,
MALAYSIA

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

07682/08397/REN/2022

9. DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE AUTHORIZATION

Date of renewal : Aug 8, 2022

10. DATE OF REVISION OF THE TEXT

13th January 2021
