

Kenazole Cream
Kenazole Cream USP 2%/w/w

Qualitative and quantitative composition:

Each gram of the cream contains: 20 mg ketoconazole USP.

Excipients capsule:

White soft paraffin, Liquid paraffin, Cetostearyl Alcohol, Cetomacrogol 1000, Propylene glycol, Benzyl alcohol, Sodium Acid Phosphate and Purified water

Pharmaceutical form:

White coloured, homogeneous cream, non- gritty and non-greasy on application to the skin, free from visible evidence of contamination

Pharmacology:

Pharmacotherapeutic group: Antifungal agent.

ATC Code: D01AC08

Ketoconazole, a synthetic imidazole dioxolane derivative antifungal which interferes with ergosterol synthesis and therefore alters the permeability of the cell membrane of sensitive fungi. It is reported to be fungistatic at concentrations achieved clinically. Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antimycotic activity against dermatophytes such as *Trichophyton* spp., *Epidermophyton floccosum* and *Microsporum* spp. and against yeasts, including *Malassezia* spp. and *Candida* spp. The effect on *Malassezia* spp. is particularly pronounced.

Pharmacokinetics:

Plasma concentrations of ketoconazole were not detectable after topical administration of Ketoconazole 2% w/w

Ketoconazole is rarely absorbed from the skin after topical application; quantities absorbed in inflamed skin are also of no pharmacokinetic significance.

Therapeutic indications:

Kenazole Cream is indicated for topical application in the treatment of dermatophyte infections of the skin such as tinea corporis, tinea cruris, tinea manus and tinea pedis infections due to *Trichophyton* spp, *Microsporon* spp and *Epidermophyton* spp. It is also indicated for the treatment of cutaneous candidosis (including vulvitis), tinea (pityriasis) versicolor and seborrhoeic dermatitis caused by *Malassezia* (previously called *Pityrosporum*) spp.

Posology and method of administration:

Route of administration: For Topical application.

Dosage: It is applied once or twice daily and continued for at least a few days after the disappearance of symptoms

Contraindications:

Kenazole 2%/w/w cream is contra-indicated in patients with a known hypersensitivity to ketoconazole or any excipients

Special warnings and precautions for use:

Kenazole 2%/w/w cream is not for ophthalmic use.

To prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids it is recommended to continue applying a mild topical corticosteroid in the morning and to apply Kenazole 2% cream in the evening, and to subsequently and gradually withdraw the steroid therapy over a period of 2-3 weeks.

Interaction with other medicinal products

No interactions with other drugs have been described for topical ketoconazole.

Pregnancy and lactation:

There are no adequate and well-controlled studies in pregnant or lactating women. Data on a limited number of exposed pregnancies indicate no adverse effects of topical ketoconazole on pregnancy or on the health of the foetus/newborn child. Plasma concentrations of ketoconazole are not detectable after topical application of Ketoconazole 2% Cream to the skin of non-pregnant humans. There are no known risks associated with the use of ketoconazole 2% Cream in pregnancy or lactation.

Effects on ability to drive and use machines:

No influence on the ability to drive or operate machinery

Undesirable effects:

After topical administration of ketoconazole, irritation, dermatitis, or a burning sensation has occurred.

Overdose:

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

Ingestion In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

Shelf life: 36 months from the date of manufacture.

Special precautions for storage:

Store in a dry place ,below 30°C protected from light.

Keep out of reach of children.

Nature and contents of container:

20gm cream packed in collapsible aluminium tubes in a unit carton.

Marketing authorization holder:

DAWA Limited,

Plot No. 7879/8, Baba Dogo Road, Ruaraka.

P. O. Box 16633 – 00620, Nairobi, Kenya

Marketing authorization number(s):

Kenya, license No. H2013/CTD776/109

Manufactured by:



DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
P. O. Box 16633 – 00620, Nairobi, Kenya.

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