

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ketoconazole Cream BP 2% w/w

KETOZ

Read all of this leaflet carefully because it contains important information for you.

Read all of this leaflet carefully before you start giving this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care worker or pharmacist.
- Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care worker or pharmacist.

What is in this leaflet

1. What **KETOZ** is and what it is used for
2. What you need to know before you take **KETOZ**
3. How to take **KETOZ**
4. Possible side effects
5. How to store **KETOZ**
6. Contents of the pack and other information

1. What KETOZ are and what they are used for

It is used for topical treatment of Tinea Cruris and Tinea Corporis caused by dermatomycosis and infection caused by candida species. Candiduria and Systemic candidosis.

2. What you need to know before you use KETOZ

Do not use KETOZ:

Ketoconazole 2% cream is not for ophthalmic use. If co-administered with a topical corticosteroid, 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 Ketoconazole 2% cream in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2-3 weeks.

Other medicines and KETOZ

No interaction studies have been performed.

Pregnancy and breast-feeding

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. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of ketoconazole. 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.

Driving and using machines

No effects have been reported.

3. How to use KETOZ

Ketoconazole cream is for use in adults

Tinea pedis: Ketoconazole cream should be applied to the affected areas twice daily. The usual duration of treatment for mild infections is 1 week. For more severe or extensive infections (eg involving the sole or sides of the feet) treatment should be continued until a few days after all signs and symptoms have disappeared in order to prevent relapse.

For other infections: Ketoconazole cream should be applied to the affected areas once or twice daily, depending on the severity of the infection. The treatment should be continued until a few days after the disappearance of all signs and symptoms. The usual duration of treatment is: tinea versicolor 2–3 weeks, tinea corporis 3-4 weeks.

The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks. General measures in regard to hygiene should be observed to control sources of infection or reinfection. Seborrhoeic dermatitis is a chronic condition and relapse is highly likely.

Paediatrics:

There are limited data on the use of ketoconazole 2% cream in paediatric patients.

OR

For external use only.

As directed by the physician.

4. Possible side effects

Local reactions including irritation and burning may occur. Contact allergic dermatitis has been reported. If this occurs, treatment should be discontinued.

5. How to store KETOZ

Store at temperature not exceeding 30°C. Protect from light.

Do not freeze. Do not accept if seal is broken.

Keep the tube tightly closed after use.

Puncture nozzle seal with piercing point of cap.

Keep the medicine out of reach of children.

6. Contents of the pack and other information

What **KETOZ** contain:

Cetomacrogol -1000 BP, Cetostearyl Alcohol BP, Light Liquid Paraffin BP, White Soft Paraffin BP, Propylene Glycol BP, Chlorocresol BP, Disodium Hydrogen Phosphate (Dihydrate) BP, Sodium Dihydrogen Phosphate Dihydrate BP, Disodium Edetate BP, Purified Water BP, Phosphoric Acid BP.

What KETOZ looks like and contents of the pack:

White soft cream.

15gm Tube in a carton with insert.

Manufactured by:



Factory address: 1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.

Head office: 3 - A, Shivsagar Estate,

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