

**PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
(KONAZOL) KETOCONAZOLE CREAM BP 2% W/W**

[Ketoconazole BP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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 provider or pharmacist.

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1 WHAT KETOCONAZOLE CREAM IS AND WHAT IT IS USED FOR

It is belong to an imidazole antifungal agent used in the prevention and treatment of a variety of fungal infections. It has a broad spectrum antifungal used to treat seborrheic dermatitis and fungal skin infections. It is indicated 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.

2 BEFORE YOU USE KETOCONAZOLE CREAM

Do not use ketoconazole cream. If you are possible allergic hypersensitivity to ketoconazole or any of the other ingredients. **Take special care with ketoconazole cream:** For Cutaneous administration topically use only, the cream should not be administered intravaginally or applied to the eye (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. Rub cream gently into cleansed affected area. The cream should be used in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2-3 weeks.

Using other medicines: Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. There are no known significant interactions.

Using ketoconazole cream with food and drink: Not known.

Pregnancy and breast-feeding: Pregnancy: category C. There are no adequate and well-controlled studies in pregnant women. Ketoconazole should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Lactation:** It is not known whether it administered topically could result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when using topically applied Ketoconazole products during lactation. Ask your doctor, health care provider or pharmacist. **Driving and using**

machines: None. **Important information about some of the ingredients of ketoconazole cream:** It contains as active ingredient ketoconazole BP, Excipients: Cetosteryl alcohol BP, White Soft Paraffin BP, Cetomacrogol 1000 BP, Light liquid paraffin BP, Propylene Glycol BP, Anhydrous Disodium Hydrogen Phosphate BP, Disodium Edetate BP, Purified water BP.

3 HOW TO USE KETOCONAZOLE CREAM

Always use ketoconazole cream exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

Method of administration: Cutaneous administration. **It is for use in adults.** **Tinea pedis:** The usual dose of 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 (e.g. 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:** The usual dose of 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.

Pediatric Use: Safety and effectiveness in children have not been established. Before treatment with ketoconazole cream consult a medical practitioner.

If you use more ketoconazole cream than you should: You may cause of an allergic reaction may include. Excessive topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment. In the event of accidental ingestion, supportive and symptomatic measures should be carried out. **If you forget to use ketoconazole cream:** Do not take a double dose to make up for a forgotten ketoconazole cream dose. If you stop using ketoconazole cream: If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.

4 POSSIBLE SIDE EFFECTS

Like all medicines, it can cause side effects, although not everybody gets them. 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 provider or pharmacist. Signs of an allergic reaction may include: Application site pruritus, skin burning sensation, stinging, dryness and headache.

5 HOW TO STORE KETOCONAZOLE CREAM

Keep out of the reach and sight of children. Do not store above 30°C. Protect from light. Do not Freeze. Store in the original container or carton. Do not use after the expiry date which is stated on the label carton, tube after abbreviation used for expiry date. The expiry date refers to the last day of that month. Do not use if you notice description of the visible signs of deterioration. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help to protect the environment.

6 FURTHER INFORMATION

It contains: The active substance is ketoconazole BP. Excipients: Cetosteryl alcohol BP, White Soft Paraffin BP, Cetomacrogol 1000 BP, Light liquid paraffin BP Propylene Glycol BP, Anhydrous Disodium Hydrogen Phosphate BP, Disodium Edetate BP, Purified water BP. **What ketoconazole cream looks like and contents of the pack Supplier and Manufacturer:** It is a White colour smooth cream filled in pack size: 15 gm aluminium collapsible tube is packed in a printed carton with package insert.

Manufactured by

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