

KEZORAL CREAM

Ketoconazole (2% w/w)

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What Kezoral is used for

Kezoral Cream is used for fungal and yeast infections of the skin in adults.

Infections may appear on the:

- Trunk, chest or back (*tinea Corporis*, *pityriasis versicolor*)
- Hands or feet (*Tinea pedis*)
- Scalp or face (*Seborrhoeic dermatitis*)
- Groin or genitals (*tinea cruris*)

How Kezoral works

Kezoral Cream works by killing the fungus that causes the infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Before you use Kezoral

- When you must not take it

Do not use Kezoral Cream:

- If you are allergic to propylene glycol and ketoconazole
- For eye infections

If you are not sure, talk to your doctor or pharmacist before using Kezoral Cream.

- Before you start to use it

Persons sensitive to miconazole or other imidazoles may be sensitive to ketoconazole also.

Talk to your doctor or pharmacist before using this medicine if you have recently used a cream, ointment or lotion on your skin infection that contains a steroid. You should continue to apply a mild steroid (such as hydrocortisone) cream, ointment or lotion in the morning whilst applying Kezoral Cream in the evening. The mild steroid treatment can then be gradually stopped over a period of 2-3 weeks.

- Taking other medicines

Kezoral Cream does not normally react with other medicines. However, tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

How to use Kezoral

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How much to use

This will depend on the type of infection and how serious it is.

For cutaneous candidiasis, tinea corporis, tinea cruris and pityriasis versicolor:

Once a day for at least 2 weeks

For tinea pedis

Once a day for at least 6 weeks

For seborrhoeic dermatitis

Once to twice a day for at least 4 weeks or until clinical clearing

Do not use the cream more often than your doctor has told you.

- Using Kezoral Cream

• Each tube of Kezoral Cream is sealed. You will need to use the cap to pierce the seal

- Rub the cream gently into the affected area and surrounding skin with clean fingers
- Do not put Kezoral Cream in the eyes

Kezoral Cream is non-greasy and should not stain clothes

- When to use it

Your doctor will tell you how often to use Kezoral Cream and for how long.

- How long to use it

Keep using the cream for several days after all the symptoms have gone away. This will stop the symptoms from coming back.

If your symptoms do not improve after 4 weeks, talk to your doctor.

- If you forget to use it

Do not double the dose if you forget.

- If you use too much (overdose)

If you swallow any cream, tell your doctor straight away.

While you are using it

- Things you must do

Preparing your skin

- Wash the infected skin and dry it well

Personal hygiene

- Unless the affected skin is on your hands, wash your hands with soap and water after using the cream

- Washing your hands after using the cream will stop you spreading the infection to other parts of your body or to other people

- Clothing that touches infected skin should be washed and changed often.

- Things you must not do

Do not allow other people to use your flannel or towel. This will stop them from getting your infection

Things to be careful of

Children and adolescents

Kezoral Cream is not recommended for use in children under 18 years of age.

Pregnancy and breast-feeding

Ketoconazole crosses the placenta. Adequate and well-controlled studies in human may not been done. Studies in animals have shown ketoconazole to be teratogenic. Ketoconazole is unlikely to be distributed into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Kezoral Cream is not likely to affect you being able to drive or use any tools or machines.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Kezoral Cream and tell your doctor straight away if you notice or suspect any of

the following. You may need urgent medical treatment.

Skin irritation (itching and stinging) have been reported. In rare cases, prolonged use may result in irritation of the skin.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website www.npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Kezoral

- Storage

Keep out of the sight and reach of children.

Store the cream in its original packaging. Store in a dry place below 30°C.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

A white homogenous cream

- Ingredients

- Active ingredient:
Ketoconazole 2% w/w

- Inactive ingredients:

- Methylparaben
- White soft paraffin
- Propylparaben
- Emulifying wax
- Propyl gallate
- Propyleneglycol

- MAL number

MAL19988491AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn. Bhd.

Lot 2 & 4, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

Product Registration Holder

Duopharma Manufacturing (Bangi) Sdn. Bhd.

Lot 2,4, 6, 8 & 10, Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

Date of Revision

July 2019