

ZOCON TABLET

Fluconazole (150 mg)

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What Zocon is used for

Zocon is used as anti-infective therapy

- Genital candidiasis (fungal infection of the vagina or penis)
- Acute or recurrent vaginal candidiasis (fungal infection of the vagina)
- Candidal balanitis (infection of the penis tip)
- Fungal infection of the skin including foot infection, fungal infection of the arms & legs, fungal infection of groin and yeast infections.

How Zocon works

Zocon is one of a group of medicines called "antifungals". The active substance is fluconazole.

Zocon is used to treat infections caused by fungi and may also be used to stop you from getting a candidal infection. The most common cause of fungal infections is a yeast called Candida

Before you use Zocon

- When you must not use it

Do not take Zocon if:

- If you are allergic or hypersensitive to any component of this medication.

- Pregnancy & breast feeding

Inform your doctors if you have such conditions:

- Pregnant or planning to become pregnant

Zocon tablet may cause harm to your unborn baby. You should not take Zocon tablet while you are pregnant

unless your doctor has told you to. Inform your doctor if you are pregnant or planning to become pregnant.

If you are a woman of child-bearing potential, avoid becoming pregnant during the treatment. Use effective contraception during treatment and for 1 week after treatment.

• Breast-feeding

Zocon tablet is excreted in human breast milk, hence its use in nursing mothers is not recommended. However, breast-feeding may be maintained if you took a single dose of Zocon tablet 150 mg.

Breast-feeding is not recommended after a high dose (more than 150 mg) or repeated use of Zocon tablet.

- Before you start to use it

Tell your doctor:

- If you have liver or kidney problems.
- If you suffer from heart disease, including heart rhythm problems.
- If you have abnormal levels of potassium, calcium or magnesium in your blood.
- If you develop severe skin reactions (Itching, reddening of skin or difficulty in breathing).

- Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Zocon:

- Anticoagulants (class of medicines that work to prevent the coagulation (clotting) of blood)
- Benzodiazepines (tranquilizers medication)
- Cisapride (medication to treat gastroesophageal reflux disease)
- Cyclosporine (medications to prevent organ transplant rejection)
- Hydrochlorothiazide (high blood pressure medication)
- Oral contraceptives (medicines taken by mouth to help prevent pregnancy)
- Phenytoin (drug to treat epilepsy)

- Rifabutin (antibiotic medicine to treat tuberculosis)
- Rifampicin (medication to treat bacterial infection and tuberculosis)
- Sulfonylureas (antidiabetic medicines)
- Tacrolimus (medication to prevent rejection of organ transplant)
- Terfenadine (medication used to treat allergies)
- Theophylline (drug used in therapy for respiratory diseases)
- Zidovudine (medication used to treat Human Immunodeficiency Virus (HIV) infections)
- Astemizole (medication used to treat allergies)
- Other medicines metabolized by the cytochrome P-450 system.

How to use Zocon

How much to use

Use in Adults:

The daily dose of fluconazole should be based on the nature and severity of the fungal infection. Most cases of vaginal candidiasis respond to single dose therapy. An inadequate period of treatment may lead to recurrence of active infection.

1. For the treatment of vaginal candidiasis, fluconazole 150 mg should be administered as a single oral dose. For Candida balanitis, fluconazole 150 mg should be administered as a single oral dose.

2. For skin infections including tinea pedis, corporis, cruris and candida infections the recommended dosage is 150 mg once weekly. Duration of treatment is normally 2 to 4 weeks but tinea pedis may require treatment for up to 6 weeks. In children Use at present is not recommended unless antifungal treatment is imperative and no suitable alternative agent exists.

Use in elderly:

The normal adult dose should be used. Use in renal impairment .Fluconazole is excreted predominantly in the urine as unchanged drug. No adjustments in single dose therapy are required.

Fluconazole may be taken at a 150 mg once weekly dose.

- When to use it

Your doctor will decide when it is appropriate for you to take Zocon according to the type of infection you have.

- How long to use it

- Take this medicine as stated in the leaflet without exceeding the recommended dosage.
- Follow any recommendations and advices from your doctor or pharmacist.

- If you forget to use it

- Do not double up the dosage as Zocon may give you serious side effects.

- If you use too much (overdose)

It is advisable for you to contact and inform your doctor if you did take too much Zocon.

While you are using it

- Things you must do

- Discuss with your doctor or pharmacist the dos' and don'ts' while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Take the Zocon according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

- Things you must not do

- Do not take your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during every consumption.

- Things to be careful of

- Toxic effects on the liver.
- AIDS patients more risky on severe skin reactions.
- If you are taking dosage < 400 mg/day with terfenadine.
- If you are on potential getting

proarrhythmic (more frequent occurrence of pre-existing irregular heartbeat) condition.

Side effects

Like all medicines, Zocon can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

Very common side effects:

- Dizziness, seizures
- Stomach & Intestinal disorders: abdominal pain, diarrhea, flatulence wind, nausea, (indigestion or stomach upset) and vomiting.
- Liver toxicity/disorders: Liver failure, Liver inflammation, Toxic injury to liver, jaundice.
- Skin and subcutaneous tissue (the tissue beneath the skin) disorders: rashes.
- Blood and lymphatic system disorders: Leucopenia (decreasing the number of white blood cells).
- Immune system disorders: Anaphylaxis (allergic reaction towards allergen).
- Metabolism and nutrition disorders.
- Heart disorders.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my ((Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and disposal of Zocon

- Storage

Keep Zocon out of reach of children. Store below 30°C. Keep container well closed and protect from light.

-Disposal

Do not use Zocon after the expiry date which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

-What it looks like

Pink colored circular flat beveled tablets with score on one side and plain on the other side.

-Ingredients

Active Ingredient:
Fluconazole

Inactive Ingredients:

Propyl Paraben, Methyl Paraben, Ponceau 4R Supra, Sodium Lauryl Sulphate, colloidal silicon dioxide, Starch, magnesium stearate, talc, Sodium Starch Glycollate, Dibasic calcium phosphate, Purified Water .

-MAL Number

MAL07101243AZ

Manufacturer and product registration holder

Manufactured by:

FDC Limited, L-56 / 57,
Verna Industrial. Estate,
Verna Goa – 403 722, India.

Product Registration Holder

Unimed Sdn Bhd

No. 53, Jalan Tembaga
SD5/2B Bandar Sri
Damansara 52200 Kuala
Lumpur.

Date of revision

22/5/2018

Serial number:

NPRA(R4/1)250418/00125