

AXCEL FLUCONAZOLE-150 CAPSULE

Fluconazole (150 mg)

What is in this leaflet

1. What Axcel Fluconazole-150 Capsule is used for.
2. How Axcel Fluconazole-150 Capsule works.
3. Before you use Axcel Fluconazole-150 Capsule.
4. How to use Axcel Fluconazole-150 Capsule.
5. While you are using it.
6. Side effects.
7. Storage and disposal of Axcel Fluconazole-150 Capsule.
8. Product description.
9. Manufacturer and Product Registration Holder.
10. Date of revision.

What Axcel Fluconazole-150 Capsule is used for

Axcel Fluconazole-150 Capsule is used as anti-infective therapy

- Cryptococcosis (infection with *Cryptococcus neoformans* fungus)
- Systemic candidiasis (infection of the *Candida albicans* fungus throughout the body)
- Mucosal candidiasis (fungal infection affecting the lining of the mouth, throat and denture sore mouth)
- Genital candidiasis (fungal infection of the vagina or penis)
- Prevention of fungal infection with malignancy (cancerous cells that have the ability to spread to other sites in the body)
- Dermatomycosis (a fungal infection of the skin)

How Axcel Fluconazole-150 Capsule works

Fluconazole is a triazole antifungal. Fluconazole kills the *Candida* fungi by interfering with their cell membranes. It works by stopping the fungi from producing ergosterol (an essential component of fungal cell membranes). The disruption in production of ergosterol causes holes to appear in the fungal cell membrane. The cell membranes of fungi are vital for their survival. They prevent unwanted substances from entering the cells and stop the contents of the cells from leaking out. As fluconazole causes holes to

appear in the cell membranes, essential constituents of the fungal cells can leak out. This kills the fungi and treats the infection.

Before you use Axcel Fluconazole-150 Capsule

When you must not use it

Do not take Axcel Fluconazole-150 Capsule if:

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

Before you start to use it

Tell your doctor:

- If you received terfenadine and multiple doses of 400mg fluconazole per day or higher.
- If you receive cisapride, halofantrine (medication used to treat malaria) and combination cisapride and pimozone.

Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Fluconazole-150 Capsule:

- Anticoagulants (class of medicines that work to prevent the coagulation (clotting) of blood)
- Azithromycin (antibiotic useful for the treatment of bacterial infections)
- 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)
- Pimozone (to reduce uncontrolled movements caused by Tourette syndrome)
- 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 Axcel Fluconazole-150 Capsule

How much to use

Use in Adults:

- For Cryptococcal Meningitis (fungal infection of the tissues covering the brain and spinal cord) and Cryptococcal (a type of fungus) Infections at Other Sites: Usual dose: 400 mg on the 1st day followed by 200-400 mg once daily. Duration of treatment usually takes at least 6-8 weeks for cryptococcal meningitis. Prevention of infection to reoccur in patients with Acquired Immune Deficiency Syndrome (AIDS): daily dose of at least 200 mg after a full course of primary therapy.
- For candidemia (invasive candidal infection): the usual dose is 400 mg on the 1st day followed by 200 mg daily. The dose may be increased to 400 mg daily.
- For oropharyngeal candidiasis (Candidal infection of mouth and throat): usual dose is 50-100 mg once daily for 7-14 days. If necessary, treatment can be continued for longer period in people with severely compromised immune function. For atrophic oral candidiasis (fungal infection of the mouth) related with dentures, the usual dose is 50 mg once daily for 14

AXCEL FLUCONAZOLE-150 CAPSULE

Fluconazole (150 mg)

days. For other mucosa candidal infections except genital candidiasis, the usual effective dose is 50-100 mg daily, given for 14-30 days. For prevention of infection to reoccur in people with AIDS, fluconazole may be taken at a 150 mg once weekly dose.

- For the treatment of vaginal candidiasis (vaginal yeast infection caused by *Candida* fungus), fluconazole 150 mg should be taken as a single oral dose. To reduce the incident of recurrent vaginal candidiasis, a 150 mg once monthly dose may be used. The duration of therapy should be individualized, but ranges from 4-12 months. For *Candida Balanitis* (inflammation of the head of the penis caused by *Candida* fungus), a 150 mg should be taken as a single oral dose.
- The recommended dose for prevention of candidiasis (fungal infection by *Candida* yeast) is 50-400 mg once daily. For patients at risk of systemic infection (an infection in which the pathogen is distributed throughout the body), the recommended daily dose is 400 mg once daily.
- For dermal (skin) infections: 150 mg once weekly or 50 mg once daily. Duration of treatment is normally 2-4 weeks but tinea pedis (fungal foot infection) may require treatment for up to 6 weeks. For tinea versicolor (fungal infection of the skin), the recommended dose is 300 mg once weekly for 2 weeks; a 3rd weekly dose of 300 mg may be needed in some patients, whereas in some patients, a single dose of 300-400 mg may be sufficient. An alternate dosage regimen is 50mg once daily for 2-4 weeks.

Use in Children:

The maximum adult daily dosage should not be exceeded in children. Fluconazole is taken as a single dose each day. The recommended dosage for mucosal candidiasis is 3 mg/kg

daily. Initial dose of 6 mg/kg may be used on the 1st day. For the treatment of systemic candidiasis and cryptococcal infections, the recommended dosage is 6-12 mg/kg daily, depending on the severity of the disease. For the prevention of fungal infections in people with immune compromised system following cytotoxic chemotherapy or radiotherapy, the dose should be 3-12 mg/kg daily.

Use in children below 4 weeks of age and younger:

In the first 2 weeks of life, the same mg/kg dosing as older children should be used but to be taken every 72 hours. During weeks 2-4 of life, the same dose should be given every 48 hours. Capsule is not recommended for children.

Use in elderly:

For people with kidney impairment (creatinine clearance <50 ml/min) the dosage schedule should be adjusted as described as follows.

Use in kidney impairment:

An initial dose of 50-400 mg should be given. After the initial dose, the daily dose should be based on the following table:

| Creatinine Clearance (ml/min) | Dosage Intervals / Daily Dose |
|-------------------------------|-------------------------------|
| >50 | 100% or 24 hours |
| <50 (no dialysis) | 50% or 48 hours |
| Regular haemodialysis | 100% every each dialysis |

When to use it

Your doctor will decide when it is appropriate for you to take Axcel Fluconazole-150 Capsule 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 Axcel Fluconazole-150 Capsule 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 Axcel Fluconazole-150 Capsule.

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 Axcel Fluconazole-150 Capsule 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.
- If you are on pregnancy or lactation.

Side effects

Like all medicines, Axcel Fluconazole-150 Capsule 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:

AXCEL FLUCONAZOLE-150 CAPSULE

Fluconazole (150 mg)

Very common side effects:

- Nervous system disorders: headache.
- Gastrointestinal disorders: abdominal pain, diarrhea, flatulence wind, nausea, dyspepsia (indigestion or stomach upset) and vomiting.
- Hepatobiliary disorders: hepatic (liver) toxicity.
- Skin and subcutaneous tissue disorders: rashes.
- Blood and lymphatic system disorders: Leucopenia (decrease in the number of white blood cells).
- Immune system disorders: Anaphylaxis (allergic reaction towards allergen).
- Metabolism and nutrition disorders.
- Cardiac (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 portal.bpfk.gov.my (Consumers -> Reporting).

Storage and disposal of axcel fluconazole -150 capsule

Storage

Keep Axcel Fluconazole-150 Capsule out of reach of children. Store below 30°C. Keep container well closed and protect from light.

Disposal

Do not use Axcel Fluconazole-150 Capsule 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

Axcel Fluconazole-150 Capsule is blue body cap, hard gelatin capsule, printed “**KOTRa**” on the capsule body.

Ingredients

Active Ingredient:
Fluconazole

Inactive Ingredients:
Lactose, Corn Starch, Sodium Lauryl Sulphate, Aerosil, Magnesium Stearate.

MAL Number

MAL09042407AZ

Manufacturer and product registration holder

Kotra Pharma (M) Sdn Bhd
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

Date of revision

10/06/2015

Serial Number

BPFK(R4/1)150415/00068