

PATIENT INFORMATION LEAFLET

Fluconazol cinfa 150mg capsules

Read this entire leaflet carefully before you start taking this medicine.

1. What Fluconazol cinfa is and what it is used for

Fluconazol cinfa is part of the group of medicines called “antifungals”. The active ingredient is fluconazole.

Fluconazol cinfa is used to treat fungal infections, and also can be used to prevent the onset of fungal infection. The most common cause of fungal infections is a yeast called *Candida*.

Adults

Your doctor may prescribe this medicine to treat the following types of fungal infections:

- Cryptococcal meningitis - a fungal infection of the brain.
- Coccidioidomycosis - a bronchopulmonary system disease.
- Localised *Candida* infections in the bloodstream, body organs (e.g. heart or lungs) or urinary tract.
- Mucosal candidiasis - infection of the lining of the mouth, throat or associated with dentures.
- Genital candidiasis - infection of the vagina or penis.
- Skin infections – e.g. athlete's foot, ringworm, jock itch, nail infection.

Fluconazol cinfa may also be prescribed to:

- Prevent the recurrence of cryptococcal meningitis.
- Prevent the recurrence of mucosal infections.
- Reduce the repeated occurrence of vaginal *Candida* infections.
- Prevent the spread of infections caused by *Candida* (if your immune system is weak and is not working properly).

Children and adolescents (up to 17 years)

Your doctor may prescribe this medicine to treat the following types of fungal infections:

- Mucosal candidiasis - infection of the lining of the mouth or throat.
- Localised *Candida* infections in the bloodstream, body organs (e.g. heart or lungs) or urinary tract.
- Cryptococcal meningitis - a fungal infection of the brain.

Fluconazol cinfa may also be prescribed to:

- Prevent the spread of infections caused by *Candida* (if your immune system is weak and is not working properly).
- Prevent the recurrence of cryptococcal meningitis.

2. Before taking Fluconazol cinfa

Do not take Fluconazol cinfa if you are:

- Allergic (hypersensitive) to fluconazole, any of the other ingredients in **Fluconazol cinfa** or any other medication taken to treat fungal infections. Symptoms may include itching, redness of the skin or difficulty breathing.
- Taking astemizole or terfenadin (antihistamine medications to treat allergies).
- Taking cisapride (used to treat stomach upsets).
- Taking pimozide (used to treat mental illness).
- Taking quinidine (used to treat heart arrhythmias).
- Taking erythromycin (an antibiotic to treat infections).

Take special care with Fluconazol cinfa

Tell your doctor if you

- - Have liver or kidney problems.
- - Suffer from heart disease, including heart rhythm problems.
- - Have abnormal levels of potassium, calcium or magnesium in the blood.
- - Notice serious skin reactions appearing (itching, redness of the skin or difficulty breathing).

Taking other medicines

Tell your doctor **immediately** if you are taking astemizole or terfenadin (antihistamine medications to treat allergies), cisapride (used to treat stomach upsets), pimozide (used to treat mental illness), quinidine (used to treat heart arrhythmias) or erythromycin (an antibiotic to treat infections); as these drugs should not be taken together with **Fluconazol cinfa** (see section: “Do not take **Fluconazol cinfa** if ...”).

There are some medicines that can interact with **Fluconazol cinfa**.

Make sure your doctor knows if you are taking any of the following medications:

- Rifampicin or rifabutin (antibiotics for infections).
- Alfentanil, fentanyl (used as anaesthetic).
- Amitriptyline, nortriptyline (used as antidepressants).
- Amphotericin B, voriconazole (antifungals).
- Medicines that make the blood less viscous, to prevent blood clots (warfarin or similar drugs).
- Benzodiazepines (midazolam, triazolam or similar medicines) used to help sleep or anxiety.
- Carbamazepine, phenytoin (used for seizures).
- Nifedipine, isradipine, amlodipine, felodipine and losartan (for hypertension - high blood pressure).
- Cyclosporine, everolimus, sirolimus or tacrolimus (used to prevent transplant rejection).
- Cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar drugs) used to treat cancer.
- Halofantrine (used to treat malaria).
- Statins (atorvastatin, simvastatin and fluvastatin or similar drugs) used for lowering high cholesterol levels.
- Methadone (used for pain).
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs - NSAIDs).
- Oral contraceptives.

- Prednisone (steroid).
- Zidovudine, also known as AZT; saquinavir (used in patients with HIV).
- Medicines for diabetes, such as chlorpropamide, glibenclamide, glipizide or tolbutamide.
- Theophylline (used to control asthma).
- Vitamin A (nutritional supplement).

Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Fluconazol cinsa with food and drink

You can take the medication with or without food.

Pregnancy and Breastfeeding

Tell your doctor if you are pregnant, intend to become pregnant or are breast-feeding. Do not take **Fluconazol cinsa** during pregnancy or while breastfeeding, unless otherwise directed by your doctor.

Consult your doctor or pharmacist before taking any medicine.

Driving and using machines

Before driving or operating any machinery, take into account that occasionally dizziness or seizures may occur.

Fluconazol cinsa ingredients - Important information

This product contains a small amount of lactose (milk sugar). Before taking this medicine, consult your doctor to confirm if he has previously said that you have intolerance to some sugars.

3. Taking Fluconazol cinsa

Follow the Fluconazol cinsa administration instructions exactly as provided by your doctor.

Consult your doctor or pharmacist if you have any questions.

The capsules should be swallowed whole with the aid of a glass of water. It is best to take your medicines at the same time every day.

The usual drug dosages for various types of infections are as follows:

Adults

Treating cryptococcal meningitis: 400mg the first day, then 200mg to 400mg once daily for 6-8 weeks, or longer if required. Occasionally, the dose can be increased up to 800mg.

Preventing recurrence of cryptococcal meningitis: 200mg once a day until your doctor give further advise.

Treating coccidioidomycosis: 200mg to 400mg once daily 11 months up to 24 months, or longer if necessary; sometimes increasing the dose up to 800mg

Treating internal fungal infections caused by *Candida*: 800mg the first day, then 400mg once a day until your doctor tells you to stop.

To treat infections of the mucous lining of the mouth, throat or associated with dentures.: 200mg to 400mg the first day, then 100mg to 200mg until your doctor tells you to stop.

Treating mucosal candidiasis, with the dose depending on the infection location: 50mg to 400mg once daily for 7 to 30 days until your doctor tells you to stop

To prevent infections in the mucous lining of the mouth and throat: 100mg to 200mg once daily, or 200mg three times a week, while the risk of developing an infection continues

Treating genital candidiasis: Single 150mg dose

To reduce repeated occurrences of vaginal candidiasis: Up to 3 doses of 150mg every 3 days (days 1, 4 and 7), then once a week while the risk of developing an infection continues.

Treating fungal infections of the skin or nails: Depending on the site of infection, 50mg once daily, 150mg once a week, 300 to 400mg once a week for 1 to 4 weeks (up to 6 weeks may be required for Athletes foot, continue treatment for fingernail infections until a healthy nail grows)

To prevent the spread of an infection caused by *Candida* (if your immune system is weak and is not working properly): 200mg to 400mg once a day while the risk of developing an infection continues.

Adolescents: 12 – 17 years

Follow the dose prescribed by your doctor (adult or child dosage).

Children up to 11 years

The maximum daily dose for children is 400mg daily.

The dosage is based on your child's weight in kilograms.

Mucosal candidiasis and throat infections caused by *Candida*: The dose and duration of treatment depends on the severity of the infection and its location: **Daily dosage** - 3mg per kg of body weight (6mg per kg body weight can be taken on the first day).

Cryptococcal meningitis or internal fungal infections caused by *Candida*: **Daily dosage** - 6-12mg per kg body weight.

To prevent children from getting an infection caused by *Candida* (if their immune system is not working properly): **Daily dosage** - 3-12mg per kg body weight.

Use in children less than 4 weeks old

Use in children who are 3-4 weeks old:

- The dose described in the table can be given once every 2 days. The maximum dose is 12mg per kg of body weight every 48 hours.

Use in children younger than 2 weeks old:

- The same dose as described in the table, but given once every 3 days. The maximum dose is 12mg per kg body weight every 72 hours.

Sometimes, doctors may prescribe doses different to those described. Carefully follow the dosing instructions provided by your doctor, and consult your doctor or pharmacist if you have questions.

Elderly

The usual adult dose, unless suffering from kidney problems.

Patients with kidney problems

Your doctor may change the dose, depending on how your kidneys are working.

If you take more Fluconazol cinfa than you should

Taking too many tablets at once can make you feel sick. Immediately contact your doctor or nearest hospital. Symptoms of a possible overdose include hearing, seeing, feeling and thinking about things that are not real (hallucinations and paranoid behaviour). It may be appropriate to initiate symptomatic treatment (with support measures and gastric lavage, if necessary).

If you forget to take Fluconazol cinfa

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take the next as soon as you remember. If there is little time before the next due dose, skip the dose you missed.

If you have any questions about using this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, **Fluconazol cinfa** can cause side effects, although not everybody gets them.

Some people develop **allergic reactions**, although serious allergic reactions are rare. If any of the following symptoms occurs, **tell your doctor immediately**.

- Sudden wheezing when breathing, shortness of breath or tightness in the chest.
- Swelling of the eyelids, face or lips.
- Itching all over the body, skin redness or itchy red spots.
- Rash.
- Severe skin reactions such as a rash causing blistering (this can affect the mouth and tongue).

Fluconazol cinfa can affect the liver. Symptoms of a possible liver problem include:

- Fatigue, Loss of appetite, Vomiting, Yellowing of the skin or whites of the eyes (jaundice).

If any of these symptoms occur, stop taking **Fluconazol cinfa** and **notify your doctor immediately**.

Other side effects:

If you think you are suffering seriously from a side effect or if you notice any other side effect not listed in this leaflet, tell your doctor or pharmacist.

Below are the common side effects, affecting 1 to 10 of every 100 patients:

- Headache, Stomach discomfort, diarrhoea, nausea, vomiting, High bleeding analysis results,
- Indicative of liver function, Rash

Below are less common side effects, affecting 1 to 10 of every 1000 patients:

- Reduction in red blood cells, making your skin pale and causing weakness or breathlessness, Decreased appetite, Inability to sleep, numbness, Convulsions, dizziness, spinning sensation, pins and needles, pricking or numbness, changes in taste sensation, Constipation, indigestion, flatulence, dry mouth, Muscle pain, Liver damage and yellowing of the skin and eyes (jaundice), Skin rash, blisters (hives), itching, increased sweating, Tiredness, feeling generally unwell fever.

Below are rare side effects, affecting 1 to 10 users in every 10,000 patients:

- Lower than normal white blood cell count, reducing ability to defend against infections and bleeding, Reddish or purplish skin, which may be due to a low number of platelets or

other changes in blood cells, Changes in the blood (high levels of cholesterol, fats), Low levels of blood potassium, Tremors, Abnormal electrocardiogram (ECG), changes in the heart rate or rhythm, Liver failure, Allergic reactions (sometimes severe), including widespread rash with blisters and peeling skin, severe allergic reactions, swelling of the lips or face., Hair loss.

Notification of side effects

Contact your doctor or pharmacist if you experience any side effects, even if it is not included in this leaflet.

5. Storing Fluconazol cinfa

Keep this medicine out of the sight and reach of children.

Do not use **Fluconazol cinfa** after the expiry date stated on the carton after the letters 'EXP'. The expiry date is the last day of that month.

Do not store at a temperature above 25°C.

6. Additional information

Composition of Fluconazol cinfa

The active substance each capsule contains is 150mg of fluconazole.

The other ingredients (excipients) are:

Capsule contents: Pregelatinised corn starch, sodium potato starch, magnesium stearate, anhydrous colloidal silica, lactose monohydrate and sodium lauryl sulphate.

Capsule: Gelatin, titanium dioxide (E171), indigo carmine (E132), quinoline yellow (E104) and erythrosine (E127).

Provided in packs of 1 capsule.

Marketing authorisation holder and manufacturer

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