

Package leaflet: information for the user

Fluconazol cinsa 150 mg capsules

Read all of this leaflet carefully before you start taking this medicine, as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fluconazol cinsa is and what it is used for.
2. What you need to know before taking Fluconazol cinsa.
3. How to take Fluconazol cinsa.
4. Possible side effects.
5. How to store Fluconazol cinsa.
6. Contents of the pack and other information.

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

Fluconazol cinsa belongs to a group of medicines called “antifungals”. The active agent is fluconazole.

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

Adults

You might be given this medicine by your doctor to treat the following types of fungal infection:

- Cryptococcal meningitis – a fungal infection in the brain.
- Coccidioidomycosis – a disease of the bronchopulmonary system.
- Infections caused by *Candida* found in the blood stream, body organs (e.g. heart, lungs) or urinary tract.
- Mucosal candidiasis – an infection affecting the lining of the mouth, throat or linked to the use of dentures.
- Genital candidiasis – infection of the vagina or penis.
- Skin infections – e.g. athlete's foot, ringworm, jock itch, nail infection.

You might also be prescribed Fluconazol cinsa to:

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

Children and adolescents (aged 0 to 17 years)

You might be given this medicine by your doctor to treat the following types of fungal infection:

- Mucosal candidiasis – infection affecting the lining of the mouth or throat.
- Infections caused by *Candida* found in the blood stream, body organs (e.g. heart, lungs) or urinary tract.
- Cryptococcal meningitis – a fungal infection in the brain.

You might also be prescribed **Fluconazol cinfa** to:

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

2. What you need to know before you take Fluconazol cinfa

Do not take Fluconazol cinfa

- If you are allergic to Fluconazole, other medicines you have taken to treat fungal infections or any of the other ingredients of this medicine (listed in section 6). The symptoms may include itching, reddening of the skin or breathlessness.
- If you are taking astemizole or terfenadine (antihistamines for allergies).
- If you are taking cisapride (used for stomach upsets).
- If you are taking pimozide (used for treating mental illness).
- If you are taking quinidine (used for treating heart arrhythmia).
- If you are taking erythromycin (an antibiotic for treating infections).

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluconazol cinfa:

- If you have liver or kidney problems.
- If you are suffering from heart disease, including heart rhythm problems.
- If you have abnormal levels of potassium, calcium or magnesium in the blood.
- If severe skin reactions develop (itching, reddening of the skin or breathlessness).
- If signs of “adrenal insufficiency” appear, in which the adrenal glands do not produce a sufficient amount of certain hormones, such as cortisol (chronic or prolonged fatigue, muscle weakness, appetite loss, weight loss, abdominal pain).

Other medicines and Fluconazol cinfa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor **immediately** if you are taking astemizole, terfenadine (an antihistamine for treating allergies), cisapride (used for stomach upsets) or pimozide (used for treating mental illness), quinidine (used for treating heart arrhythmia), erythromycin (an antibiotic for treating infections), since these medicines should not be taken with Fluconazol cinfa (see section: “Do not take Fluconazol cinfa”).

There are some medicines that may interact with Fluconazole. Make sure your doctor knows if you are taking any of the following medicines:

- Rifampicin or rifabutin (antibiotics for infections).
- Alfentanil, fentanyl (used as anaesthetics).
- Amitriptyline, nortriptyline (used as anti-depressants).
- Amphotericin B, voriconazole (anti-fungals).
- Medicines that thin the blood to prevent blood clots (warfarin or other similar medicines).
- Benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety.
- Carbamazepine, phenytoin (used for treating seizures).
- Nifedipine, isradipine, amlodipine, felodipine and losartan (for hypertension - high blood pressure).
- Olaparib (used to treat ovarian cancer).
- Cyclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection).
- Cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer.
- Halofantrine (medicine to treat malaria).
- Statins (atorvastatin, simvastatin and Fluvastatin or similar medicines) used for reducing high cholesterol levels.
- Methadone (used for pain).

- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs –NSAIDs–).
- Oral contraceptives.
- Prednisolone (steroid).
- Zidovudine, also known as AZT; saquinavir (used in HIV-infected patients).
- Medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide.
- Theophylline (used to control asthma).
- Vitamin A (nutritional supplement).
- Ivacaftor (used to treat cystic fibrosis).
- Amiodarone (used to treat an irregular heartbeat “arrhythmia”).
- Hydrochlorothiazide (diuretic).

Fluconazol cifa with food and drink

You can take the medicine with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take fluconazole if you are pregnant unless your doctor tells you to.

You can continue breast-feeding after taking a single dose of 150 mg of fluconazole. Stop breast-feeding if you are taking repeated doses of fluconazole.

Driving and using machines

When driving or operating machines, you should keep in mind that dizziness or seizures may occasionally occur.

Fluconazol cifa contains lactose.

If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

Fluconazol cifa contains sodium.

This medicine contains less than 1 mmol (23 mg) of sodium per capsule; it is essentially “sodium-free”.

3. How to take Fluconazol cifa

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

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

The usual recommended doses of this medicine for different infections are listed below:

Adults

Condition	Dose
To treat cryptococcal meningitis	400 mg on the first day then 200 mg to 400 mg once a day for 6 to 8 weeks or longer if needed. Sometimes the dose is increased up to 800 mg
To stop cryptococcal meningitis from coming back	200 mg once a day until your doctor tells you
To treat coccidioidomycosis	200 mg to 400 mg once a day from 11 months to 24 months or longer if needed. Sometimes the dose is increased

	up to 800 mg
To treat internal fungal infections caused by <i>Candida</i>	800 mg on the first day then 400 mg once a day until your doctor tells you
To treat mucosal infections affecting the lining of the mouth, throat or linked to the use of dentures.	200 mg to 400 mg on the first day and then 100 mg to 200 mg once a day until your doctor tells you
To treat mucosal candidiasis the dose depends on where the infection is located.	50 mg to 400 mg once a day for 7 to 30 days until your doctor tells you
To prevent recurrence of mucosal infections that affect the lining of the mouth and throat	100 mg to 200 mg once a day, or 200 mg 3 times a week, while you are at risk of developing an infection
To treat genital candidiasis	150 mg as a single dose
To reduce recurrence of genital candidiasis	150 mg every three days for a total of 3 doses (day 1, 4, and 7) and then once a week while the risk of developing an infection continues
To treat fungal infections of the skin or nails	Depending on the site of the infection 50 mg once a day, 150 mg once a week, 300 to 400 mg once a week for 1 to 4 weeks (up to 6 weeks may be needed for athlete's foot, for nail infection treatment until a healthy nail grows)
To prevent the spread of infections caused by <i>Candida</i> (if your immune system is weak and not working properly)	200 mg to 400 mg once a day while you are at risk of developing an infection

Use in children aged 12 to 17 years:

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

Use in children up to 11 years of age

The maximum dose for children is 400 mg a day.

The dose will be based on the child's weight in kilograms

Condition	Daily Dose
Mucosal candidiasis and throat infections caused by <i>Candida</i> – the dose and duration of treatment depend on the severity of the infection and where the infection is located.	3 mg per kg of body weight once a day (6 mg per kg of body weight can be given on the first day)
Cryptococcal meningitis or internal fungal infections caused by <i>Candida</i>	6 mg to 12 mg per kg of body weight once a day
To stop cryptococcal meningitis from coming back	6 mg per kg of body weight once a day
To prevent the child from developing an infection caused by <i>Candida</i> (if their immune system is weak and not working properly)	3 mg to 12 mg per kg of body weight once daily

Use in children aged 0 to 4 weeks

Use in children aged 3 to 4 weeks:

- The same dose as described above but given once every 2 days. The maximum dose is 12 mg per kg of body weight every 48 hours.

Use in children less than 2 weeks old:

- The same dose as described above but given once every 3 days. The maximum dose is 12 mg per kg of body weight every 72 hours.

Elderly patients

The usual adult dose should be given unless you have kidney problems.

Patients with kidney problems

Your doctor may modify your dose, depending on your kidney function.

If you take more Fluconazol cinfa that you should

Taking too many capsules at once may make you unwell. In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behaviour). It may be appropriate to initiate symptomatic treatment (with supportive measures and gastric lavage if necessary) We recommend taking the medicine leaflet and package to the healthcare provider.

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 it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

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

4. Possible side effects

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

Some people develop allergic reactions although serious allergic reactions are rare. If you get a side effect, talk to your doctor or pharmacist. This includes side effects not listed in this leaflet. If you get any of the following symptoms, tell your doctor immediately.

- Sudden wheezing, breathlessness or tightness in the chest.
- Swelling of the eyelids, face or lips.
- Itching all over the body, reddening of the skin or itchy red spots.
- Skin rash.
- Severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue).

Fluconazole may affect your liver. The signs of liver problems include:

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

If any of these symptoms occur, stop taking fluconazole and **tell your doctor immediately.**

Other side effects:

Additionally, if any of the following side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Common side effects (may affect up to 1 in 10 patients):

- Headache.
- Stomachache, diarrhoea, feeling sick, vomiting.
- High results of blood tests indicative of liver function.
- Skin rash.

Uncommon side effects (may affect up to 1 in 100 patients):

- Reduction in red blood cells which can make skin pale and cause weakness or breathlessness.
- Loss of appetite.
- Inability to sleep, feeling drowsy.

- Seizures, dizziness, sensation of spinning, tingling, pricking or numbness, changes in sense of taste.
- Constipation, difficult digestion, wind, dry mouth.
- Aching muscles.
- Liver damage and yellowing of the skin and eyes (jaundice).
- Wheals, blistering (hives), itching, increased sweating.
- Tiredness, general feeling of being unwell, fever.

Rare side effects (may affect up to 1 in 1,000 patients):

- Lower than normal white blood cells that help defend us against infections and blood cells that help to stop bleeding.
- Red or purple discolouration of the skin, which may be caused by a low platelet count, other blood cell changes.
- Changes in blood tests (high levels of cholesterol, fats).
- Low levels of potassium in the blood.
- Tremor.
- Abnormal electrocardiogram (ECG), changes in the heart rate or rhythm.
- Liver failure.
- Allergic reactions (sometimes severe), including widespread blistering rash and skin peeling, severe allergic reactions, swelling of the lips or face.
- Hair loss.

Unknown frequency (cannot be estimated from the available data):

- hypersensitivity reaction with skin rash, fever, inflamed glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (reaction to the medicine or rash with eosinophilia and systemic symptoms [DRESS]).

Reporting of side effects

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluconazol cinsa

Keep this medicine out of sight and reach of children.

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

Do not store at a temperature above 25°C.

Do not dispose of any medicines via waste water or household waste. If unsure, ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fluconazol cinsa contains

- The active agent is fluconazole.
Each hard capsule contains 150 mg of fluconazole.

- The other ingredients (excipients) are:

Capsule ingredients: pregelatinized maize starch, sodium carboxymethyl potato starch (type A), magnesium stearate, colloidal anhydrous silica, lactose monohydrate, and sodium lauryl sulphate.

Composition of the capsule: gelatine, titanium dioxide (E-171), indigotin (E-132), quinoline yellow (E104), and erythrosine (E-127).

Provided in packs of 1 capsule.

Marketing authorisation holder and manufacturer

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