

Fluconazole 150mg Hard Capsules

Read all of this leaflet carefully before you start taking this medicine because 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- The full name of this medicine is Fluconazole 150mg Hard Capsules but within the leaflet it will be referred to as Fluconazole Capsules.

What is in this leaflet

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1 What Fluconazole Capsules are and what they are used for

Fluconazole Capsules are one of a group of medicines called "antifungals". The active substance is fluconazole.

Fluconazole Capsules are used in adults to treat infections caused by fungi. The most common cause of fungal infections is a yeast called *Candida*.

You might be given this medicine by your doctor to treat genital thrush, infection of the vagina or penis.

2 What you need to know before you take Fluconazole Capsules

Do not take Fluconazole Capsules:

- if you are allergic to fluconazole or any of the other ingredients of this medicine (listed in section 6), or if you are allergic to other medicines you have taken to treat a fungal infection or thrush. The symptoms may include itching, reddening of the skin or difficulty in breathing
- if you are taking astemizole or terfenadine (antihistamine medicines 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 Fluconazole Capsules.

This is particularly important if:

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

- you develop signs of 'adrenal insufficiency' where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol (chronic, or long lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain).

Children and adolescents

Although this medicine is for adults it can be used in adolescents (from 12-17 years old) if treatment is essential and no suitable alternative exists, and should be taken in the same way as for adults.

Other medicines and Fluconazole Capsules

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

There are some medicines that may interact with Fluconazole Capsules.

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

- rifampicin or rifabutin (antibiotics for infections)
- alfentanil or fentanyl (used as anaesthetic)
- amitriptyline or nortriptyline (used as anti-depressant)
- amphotericin B or voriconazole (anti-fungal)
- medicines that thin the blood to prevent blood clots (warfarin or similar medicines)
- benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety
- carbamazepine or phenytoin (used for treating fits)
- nifedipine, isradipine, amlodipine, felodipine and losartan (for hypertension - high blood pressure)
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- cyclophosphamide or vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer
- halofantrine (used for treating 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 (NSAID))
- oral contraceptives
- prednisone (steroid)
- zidovudine, also known as AZT, or 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 for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats "arrhythmias")
- hydrochlorothiazide (a diuretic).

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

Fluconazole Capsules with food and drink

You can take this medicine with or without a meal.

Pregnancy, breast-feeding and fertility

You should not take Fluconazole Capsules while you are pregnant or breast-feeding unless your doctor has told you to.

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.

Driving and using machines

Fluconazole Capsules may cause dizziness or fits. If affected, do not drive or use machines.

Fluconazole Capsules contain lactose

This medicine contains a small amount of lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Fluconazole Capsules

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

The recommended dose is:

Adults

150mg as a single dose.

Swallow the capsule whole with a glass of water.

Elderly

The usual adult dose should be given.

Patients with kidney problems

The usual adult dose should be given.

How quickly will the treatment start to work?

Vaginal thrush:

Your condition should start to clear up within a few days - some women notice an improvement in one day. If your condition does not clear up within a few days you should talk to your doctor.

Thrush infection of the penis:

Your condition should start to clear up within a few days but it may take up to a week. If your condition has not cleared up after one week, you should talk to your doctor.

If you take more Fluconazole Capsules than you should

Taking too many capsules at once may make you unwell. Contact your doctor or your nearest hospital casualty department at once. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behaviour). Symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.

If you have any further questions on the use of 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.

A few people develop **allergic reactions** although serious allergic reactions are rare. If you get any of the following symptoms, **tell your doctor immediately**:

- sudden wheezing, difficulty in breathing or tightness in the chest
- swelling of 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 Capsules may affect your liver. The signs of liver problems include:

- tiredness
- loss of appetite
- vomiting
- yellowing of your skin or the whites of your eyes (jaundice).

Fluconazole Capsules may affect your adrenal glands and the levels of steroid hormones produced. The signs of adrenal problems include:

- tiredness
- muscle weakness
- loss of appetite
- weight loss
- abdominal pain.

If any of these happen, **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 (may affect up to 1 in 10 people):

- headache
- stomach discomfort, diarrhoea, feeling sick, vomiting
- increases in blood tests of liver function
- rash.

Uncommon (may affect up to 1 in 100 people):

- reduction in red blood cells which can make skin pale and cause weakness or breathlessness
- decreased appetite
- inability to sleep, feeling drowsy
- fit, dizziness, sensation of spinning, tingling, pricking or numbness, changes in sense of taste
- constipation, difficult digestion, wind, dry mouth
- muscle pain
- liver damage and yellowing of the skin and eyes (jaundice)
- wheals, blistering (hives), itching, increased sweating
- tiredness, general feeling of being unwell, fever.

Rare (may affect up to 1 in 1,000 people):

- lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes
- low blood potassium
- blood chemistry changes (high blood levels of cholesterol, fats)
- shaking
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- liver failure
- allergic reactions (sometimes severe), including widespread blistering rash and skin peeling, severe skin reactions, swelling of the lips or face
- hair loss.

Reporting of side effects

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 can also report side effects directly via the national reporting system listed in Yellow Card Scheme Website:

www.mhra.gov.uk/yellowcard

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

5 How to store Fluconazole Capsules

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

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

Do not store above 30°C.

Store in the original package to protect from moisture.

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.

6 Contents of the pack and other information

What Fluconazole Capsules contain

- The active substance is fluconazole. Each hard capsule contains 150mg fluconazole.
- The other ingredients are:

Capsule contents: Lactose monohydrate, pregelatinised maize starch, colloidal anhydrous silica, magnesium stearate.

Capsule shell: Gelatin, titanium dioxide (E171).

What Fluconazole Capsules look like and contents of the pack

- White cap and white body, size 1 hard gelatine capsule, filled with white powder.
- Fluconazole Capsules come in a blister pack containing one capsule.

Marketing Authorisation Holder

Actavis Group PTC ehf., Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland

Manufacturer

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If you would like a leaflet with larger text, please contact 01271 385257.