

Fluconazole 150 mg capsules

Package leaflet: Information for the user

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet:

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

1 What Fluconazole is and what it is used for

Fluconazole belongs to a group of drugs called "antifungal". The active substance is fluconazole.

Fluconazole is used in adults to treat infections caused by fungi. The most common cause of fungal infections is a yeast called *Candida albicans*, which lives problem free in the bodies of many women, but occasionally the natural balance that keeps the yeast under control is disturbed and this results in an infection. You might be given this medicine by your doctor to treat genital thrush, infection of the vagina or penis.

Vaginal Thrush

The most common symptoms are:

- itching around the outside of the vagina
 - soreness which becomes worse with rubbing and scratching
 - a white, non-smelling discharge from the vagina.
- Not every woman who has thrush will have all of these symptoms.

To help prevent thrush coming back it is advised that you:

- wash regularly
- gently dry yourself, as rubbing and scratching can aggravate thrush
- avoid tight synthetic clothing
- wear cotton underwear, stockings and loose-fitting clothes
- avoid perfumed soaps and bath additives
- change your sanitary protection frequently.

Thrush may be aggravated by sexual intercourse.

Thrush is not VD and is not usually passed on by sexual contact. However, thrush can be passed to your partner through sexual intercourse. If your thrush was successfully treated but keeps coming back, it is advised your partner is seen by a doctor.

Penile Thrush (Candidal Balanitis)

It is important to note that only the male partners of affected women should take this medicine.

The most common symptoms are:

- soreness and redness of the penis
- tightness of the foreskin
- an abnormal penile discharge.

Not every man who has thrush on his penis will have all of these symptoms.

2 What you need to know before you take Fluconazole

Do not take Fluconazole:

- if you are allergic to fluconazole or to any of the other ingredients of this medicine (listed in section 6) or to other medicines you have taken to treat fungal infections. The symptoms may include itching, reddening of the skin or difficulty in breathing
- if you are taking astemizole, 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)
- if you are taking amiodarone (used for treating heart problems).

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluconazole:

- if you are under 16 or over 60 years of age
- if you are taking any other medication other than "the Pill" (oral contraceptives)
- if you have had thrush more than twice in the last six months
- if you have abnormal liver function tests
- if you have any disease affecting your liver or kidney or if you have had unexplained jaundice
- if you have AIDS (you are more likely to suffer skin reactions)
- if you suffer from any other chronic disease or illness, including heart disease
- if you are prone to having an irregular heartbeat (arrhythmias). Fluconazole should be used with caution if you are also receiving medicines that influence heart rhythm
- if you have an imbalance of certain salts in the

blood (an electrolyte disorder) such as low blood concentrations of potassium, magnesium or calcium; this should be corrected prior to treatment with fluconazole

- if you receive warfarin or any other drug that affects blood clotting
- if you or your partner have had exposure to a sexually transmitted disease
- if you are unsure about the cause of your symptoms.
- if 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).
- if the fungal infection does not improve, as alternative antifungal therapy may be needed.
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Fluconazole.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Fluconazole. Stop taking Fluconazole and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Women only:

- you have abnormal or irregular vaginal bleeding or a blood-stained discharge
- you have vaginal or vulval sores, ulcers or blisters
- you are experiencing lower abdominal pain or a burning sensation on passing urine
- you are pregnant or trying to become pregnant.

Men only:

- your sexual partner does not have thrush
- you have penile sores, ulcers or blisters
- you have an abnormal penile discharge (leakage)
- your penis has started to smell
- you have pain on passing urine.

Children

Although this medicine is for adults it can be used in adolescents (from 16 to 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

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) 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) or amiodarone (used for treating heart problems) as these should not be taken with Fluconazole (see section: "Do not take Fluconazole if you").

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 anaesthetic)
- amitriptyline, nortriptyline (used as anti-depressant)
- amphotericin B, 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, phenytoin (used for treating fits)
- nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan (for hypertension - high blood pressure)
- olaparib (used for treating ovarian cancer)
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- cyclophosphamide, 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; saquinavir (used in HIV-infected patients)
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- theophylline (used to control asthma)
- tofacitinib (used for treating rheumatoid arthritis)
- tolvaptan (used to treat low levels of sodium in your blood or to slow kidney function decline)
- vitamin A (nutritional supplement)
- abrocitinib (used for treating severe dermatitis)
- lurasidone (used for treatment of mental disorders)
- ivacaftor (used for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats 'arrhythmias')
- hydrochlorothiazide (a diuretic)
- ibrutinib (used for treating blood cancer).

Fluconazole with food and drink

You can take your medicine with or without a meal.

Pregnancy and 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.

If you are planning to become pregnant, it is recommended to wait a week after a single dose of fluconazole before becoming pregnant.

For longer courses of treatment with fluconazole, talk to your doctor on the need for appropriate contraception during treatment which should continue for one week after the last dose.

You should not take Fluconazole if you are pregnant, think you may be pregnant, are trying to become pregnant or breast-feeding, unless your doctor has told you so.

Fluconazole taken during the first or second trimester of pregnancy may increase the risk of miscarriage.

Fluconazole taken during the first trimester may increase the risk of a baby being born with birth defects affecting the heart, bones and/or muscles.

There have been reports of babies born with birth defects affecting the skull, ears, and bones of the thigh and elbow in women treated for three months or more with high doses (400-800 mg daily) of fluconazole for coccidioidomycosis. The link between fluconazole and these cases is not clear.

You can continue breast-feeding after taking a single dose of 150 mg Fluconazole. You should not breast-feed if you are taking a repeated dose of Fluconazole.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

When driving vehicles or using machines, it should be taken into account that occasionally dizziness or fits may occur.

Important information about some of the ingredients of Fluconazole

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3 How to take Fluconazole

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

Swallow the capsule whole with a glass of water.

Adults (aged 16 to 60 years of age)

150 mg as a single dose.

Use in children and adolescents

Not recommended in children aged under 16 years.

The Elderly

Not recommended for use in patients over 60 years of age.

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 go back to your doctor.

Penis thrush infection

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 go back to your doctor.

If you take more Fluconazole 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 forget to take Fluconazole

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 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 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 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, stop taking this medicine and **tell your doctor immediately**.

Stop taking Fluconazole and seek medical attention immediately if you notice any of the following symptoms:

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

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 people)

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

Uncommon side effects: (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
- wheals, blistering (hives), itching, increased sweating
- tiredness, general feeling of being unwell, fever.

Rare side effects: (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
- hair loss.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Fluconazole

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

Do not store above 30°C. Do not transfer the capsule to another container.

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

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.
- The other ingredients are: lactose, maize starch, colloidal anhydrous silica, sodium laurilsulfate and magnesium stearate. The capsule shell contains gelatin and the colours brilliant blue (E133) and titanium dioxide (E171).

What Fluconazole capsules look like and contents of the pack:

- Hard gelatin capsules filled with white to yellowish white homogeneous powder, with a light blue opaque cap and light blue opaque body.
- Fluconazole 150 mg Capsule is available in a blister pack containing 1 capsule.

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Manufacturer

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