

Package leaflet: Information for the user

Fluconazole 150mg Hard Capsules

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

This medicine is available without prescription. Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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

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2. What you need to know before you take Fluconazole 150 mg Hard Capsules
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1. What Fluconazole 150mg Hard Capsules are and what they are used for

The active substance is fluconazole. Fluconazole is one of a group of medicines called “antifungals”.

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

Fluconazole is used to treat a fungal infection called vaginal thrush (in women), and associated candidal balanitis (in men).

What is vaginal thrush?

Vaginal thrush is caused by tiny yeast called *Candida*. Many women have the yeast living quite happily and problem-free within their bodies. However, the natural balance that keeps *Candida* under control can be upset by other factors, e.g. antibiotics, diabetes, poor general health, the Pill, or damage to vaginal tissues. Then the levels of yeast become too high and thrush develops. The most common symptoms are:

- Itching around the outside of the vagina.
- Soreness which becomes worse with rubbing and scratching. Also the salt in urine can sting the sore tissue.
- A white, non-smelling discharge from the vagina.

Not every woman who has thrush will have all of these symptoms. Some general advice to help stop thrush coming back:

- Wash regularly, but do not wash and dry yourself too harshly.
- Avoid tight clothing.
- Wear cotton underwear and stockings rather than tights.

- Avoid perfumed soaps, bath additives and vaginal deodorants.
- Change your tampon frequently as a blood-soaked tampon can provide ideal conditions for yeast growth.

Sexual intercourse can damage delicate tissue and aggravate thrush. Vaginal thrush is not “VD”, but may be passed on to your partner through intercourse. If your attack of thrush was successfully treated, but keeps coming back, your partner may need to take Fluconazole 150mg Hard Capsules himself. If you are unsure why your thrush keeps coming back, or are unsure if your partner has thrush, you or your partner should see a doctor.

What is candidal balanitis?

Candidal balanitis (penile thrush) is caused by yeast called *Candida*. Balanitis is the medical term used to describe inflammation of the end of the penis. The foreskin may also be inflamed.

Thrush can be passed on from your partner through sexual intercourse.

(Thrush is not “VD” - see “What is vaginal thrush?”). The most common symptoms are:

- Soreness, redness and irritation of the penis.
- Tightness of the foreskin.
- A white, non-smelling discharge from the penis.
- Not every man who has candidal balanitis will have all of these symptoms.

2. What you need to know before you take Fluconazole 150mg Hard Capsules

Do not take Fluconazole 150 mg Hard Capsules if you

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

Do not use Fluconazole 150mg Hard Capsules without first consulting your doctor or pharmacist:

- If you are under 16 years or over 60 years of age.
- If you are allergic to any of the ingredients in Fluconazole 150mg Hard Capsules or other antifungals and other thrush treatments.
- If you are taking any other medicine other than the Pill.
- If you are taking the antihistamine terfenadine or the prescription medicine cisapride.
- If you have had thrush more than twice in the last six months.
- If you have any disease or illness affecting your liver or kidneys or have had unexplained jaundice.
- If you have a condition that can affect the rhythm of your heart beat.
- If you suffer from any other chronic disease or illness.
- 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 you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Fluconazole Capsules

Serious skin reactions including Stevens-Johnson syndrome and **drug reaction with eosinophilia and systemic symptoms (DRESS)** have been reported in association with Fluconazole Capsules treatment. Stop using Fluconazole Capsules and seek medical attention immediately if you notice any of the symptoms described in section 4.

Talk to your doctor if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Women only:

- If you are pregnant, suspect you might be pregnant or are breastfeeding.
- If you have any abnormal or irregular vaginal bleeding or a blood stained discharge.
- If you have vulval or vaginal sores, ulcers or blisters.
- If you are suffering from lower abdominal pain or burning on passing urine.

Men only:

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

The product should never be used again if you experience a rash or an allergic reaction following use of the product.

Other medicines and Fluconazole 150mg Hard Capsules

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) as these should not be taken with Fluconazole 150 mg Hard Capsules (see section: “Do not take Fluconazole 150 mg Hard Capsules if you”).

There are some medicines that may interact with Fluconazole 150 mg Hard Capsules. 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, felodipine, verapamil and losartan (for hypertension-high blood pressure)
- 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)
- vitamin A (nutritional supplement)
- amiodarone (used for treating uneven heartbeats 'arrhythmias')
- hydrochlorothiazide (a diuretic)
- ivacaftor (used for treating cystic fibrosis)

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

Taking Fluconazole 150 mg Hard Capsules with food and drink

You can take your medicine with or without a meal.

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.

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, unless your doctor has told you so. If you become pregnant while taking this medicine or within 1 week of the most recent dose, contact your doctor

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.

Driving and using machines

When driving vehicles or using machines, it should be taken into account that occasionally dizziness or fits may occur. If affected do not drive or use machines.

Fluconazole Capsules contain lactose and sunset yellow (E110)

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, please contact your doctor before taking this medicine.

The capsule also contains sunset yellow (E110), which may cause allergic reactions, including asthma, in some people. This is more common in people who are allergic to aspirin.

3. How to take Fluconazole 150mg Hard Capsules

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Swallow the capsule whole with a glass of water. It can be taken with or without food.

Adults and young people aged over 16 years

The whole course for the treatment of thrush in men or women is one 150mg capsule.

Elderly

This product is not recommended for self-medication in the elderly. If you are over 60 years old, please do not take this capsule. Instead you should discuss your symptoms with your doctor.

Children under 16 years old

This product is not recommended for self-medication in children under 16 years old. If you are under 16 years old, please do not take this capsule. Instead you should discuss your symptoms with your doctor.

If you take too many capsules

You only need to take one capsule. If you or someone else swallows several of these capsules all together, contact your doctor, pharmacist or hospital emergency department immediately. Always take any capsules left over with you and also the box, as this will allow easier identification of the capsules.

When you should start to feel better

Your condition should start to improve within a few days. If your symptoms do not clear up within a week or you think that the capsule has not worked properly, please speak to your doctor. If you experience another attack of thrush after seven days you can use the capsule again. It might also be worth getting your partner to use this medicine or to see a doctor. Thrush is not a sexually transmitted disease but both partners can suffer from it, even if they do not have any symptoms. If you experience more than two attacks of thrush within 6 months you should tell your doctor.

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).
- reddish patches on the trunk, the patches are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).

Fluconazole 150 mg Hard 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, stop taking Fluconazole 150 mg Hard Capsules 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: 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 1000 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
- blood chemistry changes (high blood levels of cholesterol, fats)
- low blood potassium
- 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 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 150mg Hard 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 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 150 mg Hard Capsules contains

- The active substance is fluconazole.

- Each hard capsule contains 150 mg of fluconazole.
- The other ingredients are:

Capsule content: lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, colloidal anhydrous silica, magnesium stearate and sodium lauryl sulfate.

Capsule shell composition: titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110) and gelatin.

What Fluconazole 150 mg Hard Capsules look like and contents of the pack

Fluconazole 150 mg Hard Capsules are yellow capsules.

Fluconazole 150 mg Hard Capsules are available in a blister pack containing 1 capsule.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Reference number
Fluconazole 150mg Hard Capsules	PL 29831/0318

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

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