

# FLUCONAZOLE CAPSULES 150 MG

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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## **1. WHAT FLUCONAZOLE 150 IS AND WHAT IT IS USED FOR**

Fluconazole, the active ingredient, belongs to a group of medicines called anti-fungal agents and it is used to treat infections caused by fungi and yeasts. The most common cause of fungal infections is a yeast called *Candida*.

Fluconazole 150 is used to treat vaginal thrush (in women) and candidal balanitis (in men).

### **What is vaginal thrush?**

Vaginal thrush is caused by a tiny yeast called *Candida*. Many women have the yeast living quite happily and problem-free within their bodies, but when something happens to upset the natural balance that keeps *Candida* under control, candidal infections occur. 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.

Some general advice to help stop thrush coming back:

- Wash regularly
- Avoid tight clothing.
- Wear cotton underwear and stockings rather than tights.
- Avoid perfumed soaps and bath additives.

### **What is candidal balanitis?**

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

The most common symptoms are:

- Soreness and redness 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. BEFORE YOU TAKE FLUCONAZOLE 150**

### **Do not take if:**

- You have ever had an allergic reaction to fluconazole, any of the other ingredients detailed in Section 6, or to a similar medicine you have taken to treat a fungal infection e.g. Ketoconazole or to related azoles such as astemizole.
- You are taking terfenadine or astemizole (antihistamines), cisapride (used for stomach upsets), pimozide (a psychiatric medicine) or quinidine (for heart disease).
- You are under 16 years of age

### **Take special care and check with your doctor before taking if you:**

- have had thrush more than twice in the last six months
- have any disease or illness affecting your liver or kidneys or have had unexplained jaundice
- suffer from any other chronic disease or illness
- or your partner have had exposure to a sexually transmitted disease
- are unsure about the cause of your symptoms

### *Women only:*

- You have any abnormal or irregular vaginal bleeding or a blood stained discharge.
- You have vulval or vaginal sores, ulcers or blisters.
- You are experiencing lower abdominal pain or burning on passing urine.

### *Men only:*

- Your sexual partner does not have vaginal 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.

### Taking other medicines

The following if taken with fluconazole may interfere with the action of your medicine:

- Cisapride (for stomach upsets)
- Terfenadine or astemizole (antihistamines)
- Pimozide (a psychiatric medicine)
- Quinidine or calcium channel blockers (for heart disease).
- Rifampicin, rifabutine, azithromycin or erythromycin (antibiotics)
- Diuretics eg hydrochlorothiazide (used to treat fluid retention and high blood pressure)
- Losartan (used to treat high blood pressure)
- Warfarin or coumarin-type anticoagulant medicines (used to prevent blood clots)
- Benzodiazepines eg midazolam (used as tranquilisers)
- Oral sulphonylureas eg chlorpropamide, glibenclamide, glipizide or tolbutamide (used to control diabetes)

- Phenytoin or carbamazepine (used to control epilepsy)
- Ciclosporin, everolimus, sirolimus or tacrolimus (used to affect the immune response)
- Theophylline (used to control asthma)
- Zidovudine, also known as AZT, or saquinavir (used in HIV infected patients)
- Prednisone (used to treat allergies)
- Oral contraceptives
- Opioids such as alfentanil, fentanyl and methadone (used for pain relief or anaesthesia)
- Non-steroidal anti-inflammatory medicines such as aspirin, celecoxib
- The anti-depressants amitriptyline and nortriptyline
- Amphoterin B, voriconazole (used to treat fungal infections)
- Cyclophosphamide and vinca alkaloids (used in chemotherapy)
- Halofantrine (used to treat malaria)
- HMG-CoA reductase inhibitors (used to lower cholesterol)
- Vitamin A

You should also tell your doctor or pharmacist about any other medicines that you are taking, including medicines obtained without a prescription.

### **Taking Fluconazole 150 with food and drink**

You may take the capsule with or without a meal.

### **Pregnancy and breast-feeding**

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

You should not take Fluconazole 150 if you are pregnant, think you may be pregnant, are trying to become pregnant or breast-feeding.

### **Driving and using machines**

Do not drive or use machines if you experience dizziness or seizures after using this product.

### **Important information about some of the ingredients of Fluconazole 150**

This medicine contains lactose. If your doctor has told you that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

## **3. HOW TO TAKE FLUCONAZOLE 150**

Always take Fluconazole 150 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose is one capsule. Swallow the capsule whole with a drink of water.

### **How quickly will the treatment start to work?**

**Vaginal thrush:** Your symptoms 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.

***Candidal Balanitis:*** Your symptoms should start to clear up within a few days but it may take up to 1 week. If your symptoms persist after 1 week you should consult your doctor.

**If you take more capsules than you should:**

You need to take only one capsule. Taking more than this is unlikely to be dangerous unless many capsules are taken at once.

In that case, contact your doctor or the hospital casualty department as soon as possible.

**4. POSSIBLE SIDE-EFFECTS**

Like all medicines Fluconazole 150 may sometimes cause side-effects, although not everybody gets them.

If you experience a rare (these may affect between 1 in 1,000 and 1 in 10,000 patients) but serious allergic reaction (sudden wheeziness, difficulty breathing or tightness in the chest, swelling of the eyelids, face or lips, blisters or red itchy spots on the skin, itch all over the body, sores around the mouth, eyes, nose or genitals, liver disease) to fluconazole, stop taking the medication and contact your doctor immediately.

**Very common side effects** (these may affect more than 1 in 10 patients):

Headache, skin rash, nausea, vomiting, stomach pain, diarrhoea, abnormalities in liver function tests.

**Uncommon side effects** (these may affect between 1 in 100 and 1 in 1,000 patients)

Fatigue, weakness, fever, convulsions, dizziness, pins and needles, tremor, vertigo, itching, loss of appetite, constipation, indigestion, flatulence, muscle pain, dry mouth, increased sweating, sleeplessness, sleepiness, liver problems, jaundice (symptoms may include yellowing of the skin and whites of the eyes), altered sense of taste, anaemia (symptoms may include tiredness, dizziness, headache, pale skin).

**Rare side effects** (frequency more than 1 in 10,000 but less than 1 in 1000 patients)

Seizures, hair loss, liver failure, inflammation, damage or disease; blood disorders which may cause fever, tiredness, bruising and sometimes abnormal bleeding; high levels of fats or low concentration of potassium in the blood, heart rhythm disturbances and very rarely severe skin reactions.

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

**5. HOW TO STORE FLUCONAZOLE 150**

Keep out of the reach and sight of children.

Do not store above 25<sup>0</sup>C.

Do not use your medicine after the expiry date shown on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

**What FLUCONAZOLE 150 contains**

The capsule contains 150mg fluconazole as the active ingredient. The capsule also contains lactose, pregelatinised maize starch, sodium laurilsulfate, colloidal anhydrous silica, magnesium stearate, purified talc and the capsule shell also contains gelatin, water and the colours brilliant blue (E133) and titanium dioxide (E171).

**What FLUCONAZOLE 150 looks like and contents of pack**

This medicine is supplied as a pack of single blue capsule.

**Marketing Authorisation Holder and Manufacturer**

FDC International Ltd, At: Unit 6, Fulcrum 1, Solent Way, Whiteley, Fareham, Hampshire, PO15 7FE

Hard to see or read the leaflet? Call+ 44(0) 1489 565222 for help.

This leaflet was last approved in March 2013.