

## Package leaflet: Information for the user

### Fluconazole 150 mg Capsules (fluconazole)

**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 has 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 a week.

#### What is in this leaflet

1. What Fluconazole 150 mg Capsules are and what they are used for
2. What you need to know before you take Fluconazole 150 mg Capsules
3. How to take Fluconazole 150 mg Capsules
4. Possible side effects
5. How to store Fluconazole 150 mg Capsules
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#### 1. What Fluconazole 150 mg Capsules are and what they are 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 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 150 mg 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 150 mg Capsules**

### **Do not take Fluconazole 150 mg Capsules if you are**

- allergic to fluconazole, or to a similar medicine you have taken to treat a fungal infection or thrush or 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
- taking astemizole, terfenadine (antihistamine medicines for allergies)
- taking cisapride (used for stomach upsets)
- taking pimozide (used for treating mental illness)
- taking quinidine (used for treating heart arrhythmia)
- taking erythromycin (an antibiotic for treating infections)

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Fluconazole 150 mg Capsules if you

- have any disease or illness affecting your liver or kidneys
- suffer from heart disease, including heart rhythm problems
- have abnormal levels of potassium, calcium or magnesium in your blood
- develop severe skin reactions (itching, reddening of the skin or difficulty in breathing)
- 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)
- or your partner have had exposure to a sexually transmitted disease
- are unsure about the cause of your symptoms
- if the fungal infection does not improve, as alternative antifungal therapy may be needed
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Fluconazole 150 mg Capsules

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Fluconazole 150 mg Capsules treatment. Stop taking Fluconazole 150

mg Capsules and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

*Women only: If you*

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

*Men only: If*

- 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.

### **Other medicines and Fluconazole 150 mg Capsules**

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

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 Capsules (see section: “Do not take Fluconazole 150 mg Capsules if you are”).

There are some medicines that may interact with Fluconazole 150 mg Capsules. Make sure your doctor knows if you are taking any of the following medicines:

- nifedipine, isradipine, amlodipine, felodipine and losartan (for hypertension-high blood pressure)
- rifampicin, rifabutin (antibiotics for infections)
- 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
- olaparib (used for treating ovarian cancer)
- chlorpropamide, glibenclamide, glipizide or tolbutamide (used to control diabetes)
- phenytoin, carbamazepine (used for treating fits)
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection)
- theophylline (used to control asthma)
- tofacitinib (used for treating rheumatoid arthritis)
- zidovudine, also known as AZT, or saquinavir (used in HIV-infected patients)
- prednisone (steroid)
- oral contraceptives
- alfentanil, fentanyl (used as anaesthetic)
- celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID))
- amitriptyline, nortriptyline (used as anti-depressant)
- amphotericin B, voriconazole (anti-fungal)
- cyclophosphamide and 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
- vitamin A (nutritional supplement)
- methadone (used for pain)
- ivacaftor (used for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats, 'arrhythmias')
- hydrochlorothiazide (a diuretic)

### **Fluconazole 150 mg Capsules with food, drink and alcohol**

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.

You should not take Fluconazole 150 mg Capsules if you are pregnant, think you may be pregnant, are trying to become pregnant or breast-feeding, unless your doctor has told you so. You can continue breast-feeding after taking a single dose of 150 mg Fluconazole Capsules.

You should not breast-feed if you are taking a repeated dose of Fluconazole 150mg Capsules.

Fluconazole taken during the first trimester of pregnancy may increase the risk of miscarriage. Fluconazole taken at low doses during the first trimester may slightly increase the risk of a baby being born with birth defects affecting the bones and/or muscles.

### **Driving and using machines**

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

### **Fluconazole 150 mg Capsules contain lactose (milk sugar)**

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.

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

## **3. How to take Fluconazole 150 mg Capsules**

Adults aged 16-60 years: the dose is one capsule. Swallow the capsule whole with a glass of water.

Not recommended for use in children under 16 years or adults over 60 years.

Consult your doctor if symptoms have not been relieved within 1 week of taking this medicine.

If symptoms worsen at any time talk to your doctor.

### **If you take more Fluconazole 150 mg Capsules than you should**

Contact your doctor or the nearest hospital as soon as possible.

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.

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

If you experience any of the following serious allergic reactions (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), fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (Drug Reaction or rash with Eosinophilia and Systemic Symptoms (DRESS) to Fluconazole 150 mg Capsules, you should STOP taking the medication and contact your doctor IMMEDIATELY.

Fluconazole 150 mg 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 150 mg 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 150mg Capsules and **tell your doctor immediately.**

Stop taking Fluconazole 150mg Capsules 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
- 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 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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 150 mg Capsules**

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

Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton 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 150 mg Capsules contains**

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

**Capsule content:** lactose monohydrate, maize starch, colloidal anhydrous silica, magnesium stearate and sodium lauryl sulphate.

**Capsule shell composition:** Gelatin, patent blue (E131) and titanium dioxide (E171) as colouring agents.

**Black printing ink contains:** shellac, propylene glycol and black iron oxide (E172).

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

Fluconazole 150 mg Capsules are blue/ blue coloured capsules printed with 'RANBAXY'.  
Fluconazole 150 mg Capsules are available in a blister strip in a pack of 1 capsule.

### **Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

Ranbaxy (UK) Limited  
5<sup>th</sup> floor, Hyde Park, Hayes 3  
11 Millington Road  
Hayes, UB3 4AZ  
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**Manufacturers**

Sun Pharmaceutical Industries Europe B.V.  
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2132 JH Hoofddorp  
The Netherlands

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Cluj-Napoca, 400 632  
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