

## **Package leaflet: Information for the patient**

### **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
6. Contents of the pack and other information

#### **1. What Fluconazole 150 mg Capsules are and what they are used for**

Fluconazole 150 mg Capsules are one of a group of medicines called “antifungals”. The active substance is fluconazole.

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
- 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)

### **Warnings and precautions**

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

- 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 (yellowing of the skin and whites of the eyes)
- have liver or kidney problems
- suffer from heart disease, including heart rhythm problems
- have abnormal levels of potassium, calcium or magnesium in your blood
- if you 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)
- if you or your partner have had exposure to a sexually transmitted disease
- if you 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

**Other medicines and Fluconazole 150 mg Capsules**

Tell your doctor or pharmacist **immediately** if you are taking astemizole, terfenadine (an antihistamine for treating allergies), cisapride (used for stomach upsets), pimozide (used for treating mental illness), 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”).

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:

- rifampicin or rifabutin (antibiotics for infections)
- alfentanil, fentanyl (used as anaesthetic)
- amiodarone (used for treating uneven heartbeats, ‘arrhythmias’)
- amitriptyline, nortriptyline (used as anti-depressant)
- amphotericin B, voriconazole (anti-fungal)
- medicines that thin the blood to prevent blood clots (warfarin, indanedione 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, hydrochlorothiazide 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)
- ivacaftor (used for treating cystic fibrosis)
- hydrochlorothiazide (a diuretic)

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

### **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.

### **Driving and using machines**

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

### **Fluconazole 150 mg 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, please contact your doctor before taking this medicine.

## **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 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 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.**

**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 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](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 150mg 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  
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### **Manufacturers**

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