

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

### **FLUCONAZOLE CAPSULES 50 MG FLUCONAZOLE CAPSULES 200 MG**

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **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, 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*.

#### **Adults**

You might be given this medicine by your doctor to treat the following types of fungal infections:

- Cryptococcal meningitis – a fungal infection in the brain
- Coccidioidomycosis – a disease of the bronchopulmonary system
- Infections caused by *Candida* and found in the blood stream, body organs (e.g. heart, lungs) or urinary tract
- Mucosal thrush - infection affecting the lining of the mouth, throat and denture sore mouth
- Genital thrush – infection of the vagina or penis
- Skin infections - e.g. athlete's foot, ringworm, jock itch, nail infection

You might also be given Fluconazole to:

- stop cryptococcal meningitis from coming back
- stop mucosal thrush from coming back
- reduce recurrence of vaginal thrush
- stop you from getting an infection caused by *Candida* (if your immune system is weak and not working properly)

#### **Children and adolescents (0 to 17 years old)**

You might be given this medicine by your doctor to treat the following types of fungal

infections:

- Mucosal thrush - infection affecting the lining of the mouth, throat
- Infections caused by Candida and found in the blood stream, body organs (e.g. heart, lungs) or urinary tract
- Cryptococcal meningitis – a fungal infection in the brain

You might also be given Fluconazole to:

- stop you from getting an infection caused by Candida (if your immune system is weak and not working properly)
- stop cryptococcal meningitis from coming back

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUCONAZOLE**

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

- You have ever had an allergic reaction 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.
- You are taking terfenadine or astemizole (antihistamine medicines for 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).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Fluconazole

- if you have any disease or illness affecting your liver or kidneys
- if you suffer from heart disease, including heart rhythm problems
- if you 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)
- 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)

### **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) 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:

- nifedipine, isradipine, amlodipine, felodipine and losartan (for hypertension-high blood

pressure)

- rifampicin, rifabutine (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 anaesthesia)
- celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID))
- amitriptyline and 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 with food and drink**

You may take the capsule with or without a meal.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant, are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take Fluconazole while you are pregnant unless your doctor has told you to.

You can continue breast-feeding after taking a single dose of Fluconazole up to 150 mg.

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

### **Driving and using machines**

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

### **Fluconazole contains lactose (milk sugar) and sodium (salt)**

This medicine contains a small amount of lactose (milk sugar). If your doctor has told you that you have an intolerance to some sugars, such as lactose, please contact your doctor before taking this medicine.

Fluconazole capsules contain less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'

### 3. HOW TO TAKE FLUCONAZOLE

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

Swallow the capsule whole with a glass of water. It is best to take your capsules at the same time each day.

The recommended doses of this medicine for treatment of the different infections are as below:

#### Adults:

Condition	Dose
To treat cryptococcal meningitis	400 mg on the first day then 200 mg to 400 mg once daily for 6 to 8 weeks or longer if needed. Sometimes doses are increased up to 800 mg
To stop cryptococcal meningitis from coming back	200 mg once daily until you are told to stop
To treat coccidioidomycosis	200 mg to 400 mg once daily from 11 months for up to 24 months or longer if needed. Sometimes doses are increased up to 800 mg
To treat internal fungal infections caused by <i>Candida</i>	800 mg on the first day then 400 mg once daily until you are told to stop
To treat mucosal infections affecting the lining of mouth, throat and denture sore mouth	200 mg to 400 mg on the first day then 100 mg to 200 mg until you are told to stop
To treat mucosal thrush – dose depends on where the infection is located	50 mg to 400 mg once daily for 7 to 30 days until you are told to stop
To stop mucosal infections affecting the lining of mouth, throat from coming back	100 mg to 200 mg once daily, or 200 mg 3 times a week, while you are at risk of getting an infection
To treat genital thrush	150 mg as a single dose

To reduce recurrence of vaginal thrush	150 mg every third day for a total of 3 doses (day 1, 4 and 7) and then once a week for 6 months while you are at risk of getting an infection
To treat fungal skin and nail infections	Depending on the site of the infection 50 mg once daily, 150 mg once weekly, 300 to 400 mg once weekly for 1 to 4 weeks (Athlete's foot may be up to 6 weeks, for nail infection treatment until infected nail is replaced)
To stop you from getting an infection caused by <i>Candida</i> (if your immune system is weak and not working properly)	200 mg to 400 mg once daily while you are at risk of getting an infection

#### **Adolescents from 12 to 17 years old**

Follow the dose prescribed by your doctor (either adults or children posology).

#### **Children to 11 years old**

The maximum dose for children is 400 mg daily.

The dose will be based on the child's weight in kilograms.

<b>Condition</b>	<b>Daily dose</b>
Mucosal thrush and throat infections caused by <i>Candida</i> – dose and duration depends on the severity of the infection and on where the infection is located	3 mg per kg of body weight (6 mg per kg of body weight might be given on the first day)
Cryptococcal meningitis or internal fungal infections caused by <i>Candida</i>	6 mg to 12 mg per kg of body weight
To stop children from getting an infection caused by <i>Candida</i> (if their immune system is not working properly)	3 mg to 12 mg per kg of body weight once daily

#### **Use in children 0 to 4 weeks of age**

Use in children of 3 to 4 weeks of age:

The same dose as above but given once every 2 days. The maximum dose is 12 mg per kg of body weight every 48 hours.

Use in children less than 2 weeks old:

The same dose as above but given once every 3 days. The maximum dose is 12 mg per kg of body weight every 72 hours.

## **Elderly**

The usual adult dose should be given unless you have kidney problems.

## **Patients with kidney problems**

Your doctor may modify your dose, depending on your kidney function.

## **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 forgot 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 Fluconazole may sometimes cause side-effects, although not everybody gets them.

A few people develop **allergic reactions** although serious allergic reactions are rare. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. If you get any of the following symptoms, **tell your doctor immediately.**

- sudden wheeziness, difficulty breathing or tightness in the chest
- swelling of the eyelids, face or lips
- itching all over the body, reddening of the skin or itchy red spots
- hypersensitivity reaction with skin rash, 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)).
- 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)

If any of these happen, stop taking Fluconazole 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) are:

- 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) are:

- 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) are:

- 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 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**

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not use your medicine after the expiry date shown on the carton after EXP. The

expiry date refers to the last day of the month.

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. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What FLUCONAZOLE contains**

Fluconazole 50mg Capsules contain 50mg fluconazole as the active ingredient.

Fluconazole 200mg Capsules contain 200mg fluconazole as the active ingredient. The capsules also contain lactose, pregelatinised maize starch, sodium laurilsulfate, colloidal anhydrous silica, magnesium stearate and purified talc. The capsule shells also contain gelatin, sodium laurilsulfate, water and the colours brilliant blue (E133), titanium dioxide (E171) and erythrosine (E127).

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

The 50mg capsules are blue and white and the 200mg capsules are violet and white.

Both the 50mg and 200mg capsules are supplied in packs containing 7 capsules.

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

FDC International Ltd, 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 revised in February 2020.