

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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# Flukonazol

50mg Capsules , 150mg Capsules

## FLUCONAZOLE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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### What is in this leaflet?

1. What Flukonazol Capsules are and what they are used for
2. Before you take Flukonazol Capsules
3. How to take Flukonazol Capsules
4. Possible side effects
5. How to store Flukonazol Capsules

### 1. WHAT FLUKONAZOL CAPSULES ARE AND WHAT THEY ARE USED FOR

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.

#### 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 Flukonazol Capsules 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 Flukonazol Capsules 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. BEFORE YOU TAKE FLUKONAZOL CAPSULES**

### ***Do not take Flukonazol Capsules if you***

- are allergic (hypersensitive) to fluconazole, to other medicines you have taken to treat fungal infections, or any of the other ingredients of Flukonazol Capsules. 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)

If any of the above apply to you and you have not already discussed this with your doctor or pharmacist, you should do so as soon as possible and before taking Flukonazol Capsules.

### ***Take special care with Flukonazol Capsules***

Tell your doctor if you

- have liver or kidney problems
- 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)

### ***Taking 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 Flukonazol Capsules (see section: “Do not take Flukonazol Capsules”).

There are some medicines that may interact with fluconazole. 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 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)

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

Taking Flukonazol Capsules with food and drink You can take your medicine with or without a meal.

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

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding. You should not take fluconazole while you are pregnant or breast-feeding unless your doctor has told you to.

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

### ***Driving and using machines***

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

### ***Important information about some of the ingredients of Flukonazol Capsules***

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 medicinal product.

### ***3. HOW TO TAKE FLUKONAZOL CAPSULES***

Always take your medicine 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 usual doses of this medicine for different infections are 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	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.

Condition	Daily dose
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	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

#### **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.

Doctors sometimes prescribe different doses to these. Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### **Elderly**

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

#### ***Patients with kidney problems***

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

#### ***If you take more Flukonazol Capsules 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 Flukonazol Capsules***

Do not take a double dose to make up for a forgotten dose. If you forget 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, Flukonazol Capsules 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).

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 Flukonazol 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**, which affect 1 to 10 users in 100 are listed below:

- Headache
- Stomach discomfort, Diarrhoea, Feeling sick, Vomiting
- Increases in blood tests of liver function
- Rash

**Uncommon side effects**, which affect 1 to 10 users in 1,000 are listed below:

- 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**, which affect 1 to 10 users in 10,000 are listed below:

- 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

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 FLUKONAZOL CAPSULES

Keep out of the reach and sight of children. Do not store above 25°C. Store in the original package. Do not use Flukonazol Capsules after the expiry date which is stated on the carton after expiry date. The expiry date refers to the last day of that 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.

This leaflet was last revised in July 2014