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CP.FLC.JNT.C.POM.IS.V10P1

**PATIENT INFORMATION LEAFLET**

**FLUCONAZOLE 50mg CAPSULES**

**KENT PHARMA**

**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 or your 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. 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 is one of a group of medicines called antifungal agents. Fluconazole is used to treat infections caused by fungi/yeasts. The most common cause of fungal infection is yeast called *Candida*.

**Adults**

You may be given Fluconazole to treat fungal infections such as:

- Thrush of the mouth or throat (mucosal infections)
- Skin infections (e.g. athlete's foot, ringworm, nail infection)
- Internal (systemic) fungal infections caused by *Candida*, e.g. infections of the blood stream, urinary tract or other body organs
- Internal (systemic) fungal infections caused by *Cryptococcus*, e.g. cryptococcal meningitis and infections of other sites such as the lungs and skin
- Genital *Candida* infections like vaginal thrush or candidal balanitis (inflammation of the end of the penis and/or foreskin)
- Coccidioidomycosis (disease of the bronchopulmonary system)

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 may also be given Fluconazole to:

- Stop you from getting a fungal infection (if your immune system is not working properly)
- Stop an infection caused by *Cryptococcus* from coming back

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

**Do not take Fluconazole if you:**

- are allergic (hypersensitive) to fluconazole, or another drug from the same group of antifungal drugs (i.e. imidazole's), or any of the other ingredients of Fluconazole Capsules (See section 6). Symptoms can include itching, reddening of the skin or difficulty in breathing
- are taking another drug called terfenadine or astemizole (antihistamines), cisapride (a drug used to treat acid reflux, indigestion or decreased gastric motility), pimozide (a psychiatric medicine) or quinidine (for heart disease)
- are taking erythromycin (an antibiotic for treating infections)
- suffer from porphyria

If any of the above applies 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 Fluconazole Capsules.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Fluconazole if you:

- suffer from liver problems
- suffer from kidney problems
- suffer from heart problems, including heart rhythm problems
- have AIDS
- 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)
- If you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking fluconazole
- if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Fluconazole treatment. Stop taking Fluconazole and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

If you have any of these conditions and you have not already discussed this with your doctor or pharmacist, you should do so as soon as possible and before taking this medicine.

**Other medicines and Fluconazole**

Please tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines:

- amiodarone (used for treating uneven heartbeats 'arrhythmias')

- rifampicin or rifabutin (types of antibiotics, often used for the treatment of tuberculosis)
- erythromycin or azithromycin (types of antibiotics)
- hydrochlorothiazide (a diuretic) or eplerenone (types of diuretic or "water tablet")
- drugs which thin the blood (known as anticoagulants, e.g. warfarin)
- medicines to help you sleep (such as benzodiazepines, e.g. midazolam or triazolam)
- medicines to treat diabetes (known as sulphonylureas, e.g. chlorpropamide, glibenclamide, glipizide, tolbutamide or nateglinide)
- ciclosporin, tacrolimus, everolimus or sirolimus (drugs which suppress the immune system, which are commonly used following organ transplants)
- zidovudine (AZT), nevirapine, ritonavir, tipranavir or saquinavir (antiviral drugs, used to treat HIV)
- cisapride (a drug used to treat acid reflux, indigestion or decreased gastric motility)
- drugs used to treat psychosis (e.g. pimozide, quetiapine, sertindole)
- anti-depressants (used to treat depression, e.g. amitriptyline, nortriptyline, citalopram, reboxetine and St. John's Wort)
- drugs used to treat cancer (such as vinca alkaloids e.g. vincristine and vinblastine)
- drugs used to control levels of fat in your blood (e.g. atorvastatin, simvastatin or fluvastatin)
- calcium channel antagonists (e.g. nifedipine, amlodipine, nisoldipine, isradipine, felodipine)
- COX-II inhibitors (Non-Steroidal Anti-Inflammatory Drugs (NSAID) e.g. ibuprofen, celecoxib, flurbiprofen, naproxen, lornoxicam, meloxicam, diclofenac, rofecoxib or parecoxib)
- cyclophosphamide (a drug used to treat cancer and suppress the immune system)
- bosentan (used to treat hypertension)
- losartan (used to treat high blood pressure)
- any other drugs used to treat fungal infection (e.g. amphotericin)
- prednisone (to treat serious inflammatory diseases)
- fentanyl (used to treat severe pain)
- halofantrine (used to treat malaria)
- phenytoin or carbamazepine (used to treat epilepsy)
- terfenadine or astemizole (types of antihistamines)
- quinidine (an anti-arrhythmic heart drug)
- methadone (to help withdraw from heroin)
- vitamin A (a vitamin supplement)
- theophylline (a drug used to treat asthma)
- an oral contraceptive (the "Pill")
- alfentanil (an anaesthetic drug used in surgery)
- voriconazole (an antifungal drug)
- ivacaftor (for treatment of cystic fibrosis)
- tofacitinib (used for treating rheumatoid arthritis)
- olaparib (used for treating ovarian cancer)

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, 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 if you are pregnant, think you may be pregnant, are trying to become pregnant or breast-feeding, unless your doctor has told you so.

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**

Fluconazole Capsules are unlikely to affect your ability to drive or use machinery, however, when driving or operating machines it should be taken into account that occasionally dizziness or seizures may occur.

**Important information about some of the ingredients in your medicine**

Fluconazole Capsules contain lactose monohydrate, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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 Capsules exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The capsules should always be taken with plenty of water. They can be taken with or without food. Your dose will be dependent on the type and severity of your infection, your age, weight and kidney function. Your doctor will choose the best dose for you.

**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 the mouth, throat and denture sore mouth	200 mg to 400 mg on the first day then 100 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 the 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

**Use in children and adolescents**

The capsules formulation may be unsuitable for children under 5-6 years of age.

**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 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

**Children under 4 weeks of age**

In the first two weeks of life, the recommended dose for older children should be followed, but given every 72 hours. In weeks three and four, the recommended dose for older children should be followed, but given every 48 hours. A maximum dose of 12mg/kg every 72 hours should not be exceeded during the first two weeks of life. A maximum dose of 12mg/kg every 48 hours should not be exceeded during weeks three and four.

It is very important that you follow your doctor's instructions as to how many Fluconazole Capsules to take, how often to take them and for how long you should continue to take your capsules. Fluconazole Capsules are not suitable for all dosages described in this leaflet. Other products containing fluconazole are available for this.

**Elderly or patients with kidney problems**

Your doctor will decide what dose to give you. This may be lower than the usual adult dose depending on your kidney function.

**If you take more Fluconazole than you should**

It is important to stick to the dose on the label of your medicine. If you or someone else swallows several of these capsules all together, contact your doctor, pharmacist or hospital emergency department immediately. Always take any capsules left over with you and also the box, as this will allow easier identification of the capsules. 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**

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose. If it is almost time for your next dose do not take the dose that you missed.

**If you stop taking Fluconazole**

Even when you start to feel better it is important for you to keep on taking your capsules for as long as your doctor tells you. If you stop too soon, the infection may start up again. Sometimes your doctor may want you to continue taking your capsules to prevent your infection from coming back.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine 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 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 wheezing, difficulty in breathing or tightness in the chest (anaphylaxis)
- 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)
- Widespread rash, high body temperature and enlarged lymph node (DRESS syndrome or drug hypersensitivity syndrome)

Fluconazole 50mg capsules may affect your liver. The signs of liver problems include:

- tiredness
- loss of appetite
- vomiting
- yellowing of your skin or whites of the eyes (jaundice)

If any of these happen, stop taking Fluconazole and tell your doctor immediately.

**The following side-effects are usually mild. However, if you suffer from any of these and they are severe or prolonged, please tell your doctor or pharmacist.**

**Common: may affect up to 1 in 10 people**

- headache
- stomach discomfort, diarrhoea, feeling sick, vomiting
- increases in blood tests of liver function
- rash

**Uncommon: 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
- fits, dizziness, sensation of spinning (vertigo), tingling, pricking or numbness, changes in sense of taste
- indigestion, wind, dry mouth, constipation
- muscle pain
- increased sweating
- tiredness, general feeling of being unwell, fever
- fixed drug eruption (may look like round or oval patches of redness and swelling of the skin), blistering (hives), itching
- liver damage and yellowing of the skin and eyes (jaundice)

**Rare: 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
- oedema
- blood chemistry changes (high blood levels of cholesterol, fats)
- shaking
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- hair loss
- liver failure
- inflammation of the liver (hepatitis)
- low blood potassium

**Not known: cannot be estimated from the available data**

- Drug reaction with eosinophilia and systemic symptoms (DRESS) including fixed drug eruption

**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 website: [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 THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.**

No special storage conditions. Do not use Fluconazole Capsules after the expiry date, which is stated on the carton. 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 dispose of medicines no longer required. These measures will help to protect the environment.

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Fluconazole Capsules contain**

The active substance is fluconazole. Each capsule contains 50mg fluconazole. The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, sodium laurilsulfate, colloidal anhydrous silica and magnesium stearate.

The capsule shell contains: Titanium dioxide (E171), yellow iron oxide (E172), quinoline yellow (E104), patent blue V (E131) and gelatin.

**What Fluconazole Capsules look like and contents of the pack**

Green and white capsules. In a blister pack of 7 capsules.

**Marketing Authorisation Holder**

Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.




**Company responsible for release of this product**

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.  
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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CP.FLC.JNT.C.POM.IS.V10P1

<b>Customer:</b> IS	<b>Originated by:</b> JKG (AWG)	<b>Colours</b>
<b>Product:</b> Fluconazole 50 mg Capsules POM		 
<b>Dimensions:</b> 140mm x 500mm		
<b>Item Code:</b> CP.FLC.JNT.C.POM.IS.V10P1		
<b>Proof and Date:</b> 1 27/06/2022		
<b>Revision:</b> COO to Kent Pharma UK Limited		
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