

## **PATIENT INFORMATION LEAFLET**

### **FLUCONAZOLE 50mg AND 200mg CAPSULES**

Please read all of this leaflet carefully before you start taking this medicine.

- **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. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.**

#### **IN THIS LEAFLET**

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### **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*. 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)
- 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)

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 (in AIDS patients)

### **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. imidazoles), or any of the other ingredients of Fluconazole Capsules (See section 6, Contents of pack and other information)
- 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)
- 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.

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

- suffer from liver problems
- suffer from kidney problems
- suffer from heart problems
- have AIDS
- have imbalances in the salt levels in your blood

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.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking any of the following medicines:

- rifampicin or rifabutin (types of antibiotics, often used for the treatment of tuberculosis)
- erythromycin or azithromycin (types of antibiotics)
- hydrochlorothiazide 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, ritanovir, tipranavir, aquinavir 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 Worts)
- drugs used to treat cancer (such as vinca alkaloids e.g. vincristine and vinblastine)
- drugs used to treat migraine (such as ergot alkaloids e.g. ergotamine or methylsergide)
- drugs used to control levels of fat in your blood (e.g. atorvastatin or simvastatin)
- calcium channel antagonists (e.g. nifedipine, amlodipine, nisoldipine)
- COX-II inhibitors (non-steroidal anti-inflammatory drugs e.g. ibuprofen, celecoxib, rofecoxib or parecoxib)
- cyclophosphamide (a drug used to treat cancer and suppress the immune system)
- antimalarial drugs such as artemether and lumefantrine
- 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)
- ivabradine (used to treat angina)
- 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)

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

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

Fluconazole should not be used in pregnancy or in pregnant women of childbearing potential unless adequate contraception is used. Breast-feeding is not recommended whilst using fluconazole. Ask your doctor or pharmacist for advice before taking any medicine.

### **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.

## **3. HOW TO TAKE FLUCONAZOLE**

Always take Fluconazole Capsules exactly as your doctor has told you. You should 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**

The usual dose for the treatment of vaginal thrush or candidal balanitis is one 150mg single dose.

To treat mucosal thrush of the mouth or throat, the usual dose is 50mg-100mg once daily for up to 14 days. In other types of mucosal thrush, this may be continued for up to 30 days. If you have oral thrush associated with the use of dentures, you may be given a local antiseptic to use at the same time.

To treat fungal skin infections (e.g. athlete's foot, ringworm), the usual dose is 50mg once daily for up to 6 weeks.

For systemic (invasive) infections, the usual dose is 400mg on the first day, followed by 200mg-400mg daily. In cryptococcal infections, this may be continued for up to 8 weeks.

To prevent fungal infections in patients with poor immune systems, the usual dose is 50-400mg once daily, depending on the risk of infection.

To prevent cryptococcal infections coming back in AIDS patients, a usual dose of 100-200mg daily may be given indefinitely.

### **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.

## **Children**

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

### **Children over 4 weeks of age**

Your doctor will calculate an appropriate dose based on body weight. The usual dose for mucosal infections is 3mg/kg body weight daily. A dose of 6mg/kg may be given on the first day.

For internal infections and cryptococcal infections, the usual dose is 6-12mg/kg daily, depending on the severity of the infection. A maximum dosage of 400mg daily should not be exceeded in these cases.

To prevent fungal infections in patients with poor immune systems, a dose of 3-12mg/kg should be given daily, depending on the risk of infection. A maximum dosage of 400mg daily should not be exceeded in these cases.

### **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.

### **If you take more of your medicine 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.

### **If you forget to take your medicine**

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.

### **If you stop taking your medicine**

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, Fluconazole Capsules can cause side effects, although not everybody gets them.

**STOP taking Fluconazole Capsules straight away and contact your doctor immediately if you experience:**

- a serious allergic reaction (anaphylaxis) or hypersensitivity including an itchy rash (hives), itching, sore mouth or eyes, fever, swelling of the face, lips, throat or tongue
- a sudden wheeziness or tightness of the chest

- liver problems such as yellowing of the skin or whites of the eyes (jaundice), dark coloured urine, or changes in the way your liver works (that may show up in blood tests)
- a severe skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome)
- a severe rash with reddening, peeling and swelling of the skin that looks like a burn (toxic epidermal necrolysis).

**The following side-effects are usually mild. However, if you suffer from any of these and they are severe or prolonged, please inform 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, tingling, pricking or numbness, changes in sense of taste
- indigestion, wind, dry mouth
- muscle pain
- low blood potassium
- increased sweating
- tiredness, general feeling of being unwell, fever

**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
- blood chemistry changes (high blood levels of cholesterol, fats)
- shaking
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- 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). 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.**

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.

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 Capsules contain**

The active substance is fluconazole. Each capsule contains 50mg or 200mg fluconazole.

The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, sodium laurilsulfate, colloidal anhydrous silica and magnesium stearate.

The capsule shell contains:

50mg: titanium dioxide (E171), yellow iron oxide (E172), quinoline yellow (E104), patent blue V (E131) and gelatin.

200mg: titanium dioxide (E171) and gelatin.

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

50mg: green and white capsules. In a blister pack of 7 capsules.

200mg: white capsules. In a blister pack of 7 capsules.

### **Marketing Authorisation Holder**

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland

### **Company responsible for release of this product**

Kent Pharmaceuticals Ltd., Crowbridge Road, Ashford, Kent TN24 0GR, U.K

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

### **Distributor**

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

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