Package leaflet: Information for the user
Fluconazole 50mg, 200mg Hard Capsules

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 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 Capsules are and what they are used for
2. What you need to know before you take Fluconazole Capsules
3. How to take Fluconazole Capsules
4. Possible side effects
5. How to store Fluconazole Capsules
6. Contents of the pack and other information

1. What Fluconazole Capsules are and What they are used for

The active substance is fluconazole. 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 a 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 may 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 Capsules

Do not take Fluconazole Capsules if you

• are allergic (hypersensitive) 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
• 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)

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluconazole Capsules 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).
• 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)
• have ever developed a skin rash or skin peeling, blistering and/or mouth sores after taking Fluconazole Capsules

Serious skin reactions including Stevens-Johnson syndrome and **drug reaction with eosinophilia and systemic symptoms (DRESS)** have been reported in association with Fluconazole Capsules treatment. Stop using Fluconazole Capsules and seek medical attention immediately if you notice any of the symptoms described in section 4.

Talk to your doctor if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Other medicines and Fluconazole Capsules

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 Capsules (see section: "Do not take Fluconazole Capsules if you").

There are some medicines that may interact with Fluconazole 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)
• 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, verapamil and losartan (for hypertension-high blood pressure)
• ciclosporin, everolimus , sirolimus or tacrolimus (to prevent transplant rejection)
• cyclosphosphamide, 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)
• amiodarone (used for treating uneven heartbeats 'arrhythmias')
• hydrochlorothiazide (a diuretic)
• ivacaftor (used for treating cystic fibrosis)

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

Taking Fluconazole Capsules with food and drink
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.

If you are planning to become pregnant, it is recommended to wait a week after a single dose of fluconazole before becoming pregnant.

For longer courses of treatment with fluconazole, talk to your doctor on the need for appropriate contraception during treatment which should continue for one week after the last dose.
You should not take fluconazole if you are pregnant, think you may be pregnant, are trying to become pregnant, unless your doctor has told you so. If you become pregnant while taking this medicine or within 1 week of the most recent dose, contact your doctor.

Fluconazole taken during the first or second trimester of pregnancy may increase the risk of miscarriage. Fluconazole taken during the first trimester may increase the risk of a baby being born with birth defects affecting the heart, bones and/or muscles.

There have been reports of babies born with birth defects affecting the skull, ears, and bones of the thigh and elbow in women treated for three months or more with high doses (400-800 mg daily) of fluconazole for coccidioidomycosis. The link between fluconazole and these cases is not clear.

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

Fluconazole Capsules contain lactose and sunset yellow (E110)
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.

Fluconazole 150mg Capsules contains sunset yellow (E110), which may cause allergic reactions, including asthma, in some people. This is more common in people who are allergic to aspirin.

3. How to take Fluconazole Capsules

Always take this medicine exactly as your doctor has told you. 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 *Candida*	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	50 mg to 400 mg once daily for 7 to 30 days

infection is located	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 trush	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 *Candida* (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 *Candida* – 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 *Candida*	6 mg to 12 mg per kg of body weight
To stop children from getting an infection caused by *Candida* (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 Fluconazole 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 Fluconazole 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, 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 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).
- reddish patches on the trunk, the patches are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).

Fluconazole 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 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 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: 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
- 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: 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
- 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, pharmacist or nurse. 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 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 Capsules

Keep this medicine out of the sight and reach of children.
Do not use this medicine Fluconazole Capsules after the expiry date which is stated on the pack after EXP.
The expiry date refers to the last day of the 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 Capsules contains

- The active substance is fluconazole.
- Each hard capsule contains 50 mg or 200 mg of fluconazole.
- The other ingredients are:

Capsule content: lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, colloidal anhydrous silica, magnesium stearate and sodium lauryl sulfate.

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

200mg hard capsules: titanium dioxide (E171) and gelatin.

What Fluconazole Capsules look like and contents of the pack

50mg hard capsules: green and white capsules.
200mg hard capsules: white capsules.

Fluconazole Capsules are available in blister packs of:
50mg hard capsules: 7 capsules
200mg hard capsules: 7 capsules.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	**Reference number**
Fluconazole 50mg Hard Capsules	PL 29831/0294

Fluconazole 200mg Hard Capsules	PL 29831/0305

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer
CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

This leaflet was last revised in 01/2024.