



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FLUCOSTAT 50 CAPSULE
FLUCOSTAT 150 CAPSULE
FLUCOSTAT 200 CAPSULE

Fluconazole 50mg, 150mg and 200mg Capsules

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your healthcare provider.
- 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 any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your healthcare provider.

In this leaflet:

1. What FLUCOSTAT capsule is and what it is used for.
2. What you need to know before you use FLUCOSTAT capsule.
3. How to use FLUCOSTAT capsule.
4. Possible side effects.
5. How to store FLUCOSTAT capsule.
6. Contents of the pack and other information.

1. WHAT FLUCOSTAT CAPSULE IS AND WHAT IT IS USED FOR

Flucostat is one of a group of medicines called “antifungals”. The active substance is fluconazole.

Flucostat 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 bloodstream, 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 Flucostat 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



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FLUCOSTAT 50 CAPSULE

FLUCOSTAT 150 CAPSULE

FLUCOSTAT 200 CAPSULE

Fluconazole 50mg, 150mg and 200mg Capsules

- 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 Flucostat 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 USE FLUCOSTAT CAPSULE

Do not take Flucostat capsule if you are:

- allergic to Flucostat or to other medicines, you have taken to treat fungal infections
- taking astemizole, terfenadine (antihistamine medicines for allergies)
- taking cisapride (used for stomach upsets)
- taking pimozide (used for treating mental illness)
- are taking quinidine (used for treating heart arrhythmia)
- taking erythromycin (an antibiotic for treating infections)

Warnings and precautions

Check with your doctor or pharmacist before taking Fluconazole if you:

- Have low blood volume (hypovolaemia) or are at risk of developing low blood pressure
- Have low levels of protein in the blood (hypoproteinemia) as a result of kidney damage
- Have liver congestion (slowed blood flow through the vessels) or other liver problems
- Have kidney problems.
- Have or may have diabetes. If you are taking insulin, your doctor may need to adjust your insulin dosage.
- Are elderly, or you take other medicines which can cause the drop of blood pressure, or you have other medical conditions that are risks for the drop of blood pressure.
- Have prostate trouble or difficulty passing urine.
- Have or have had gout.
- Have an abnormal blood condition.
- Are about to undergo any blood or urine tests.

Your doctor will want to monitor you and may take blood for testing while you are taking this medicine.

Other medicines and Flucostat capsule

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 pimozone (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").



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FLUCOSTAT 50 CAPSULE

FLUCOSTAT 150 CAPSULE

FLUCOSTAT 200 CAPSULE

Fluconazole 50mg, 150mg and 200mg Capsules

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, verapamil, felodipine and losartan (for hypertension- high blood pressure)
- olaparib (used for treating ovarian cancer)
- 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 (NSAIDs))
- 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)
- tofacitinib (used for treating rheumatoid arthritis)
- tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline
- vitamin A (nutritional supplement)
- ivacaftor (used for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats 'arrhythmias')
- hydrochlorothiazide (a diuretic)
- ibrutinib (used for treating blood cancer)

Fluconazole Capsules with food

You can take your medicine with or without a meal.

Pregnancy, breast-feeding and fertility

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



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FLUCOSTAT 50 CAPSULE

FLUCOSTAT 150 CAPSULE

FLUCOSTAT 200 CAPSULE

Fluconazole 50mg, 150mg and 200mg Capsules

You should not take Fluconazole Capsules if you are pregnant, think you may be pregnant, are trying to become pregnant or breast-feeding, unless your doctor has told you so.

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

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

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.

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

Driving and using machines

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

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Fluconazole.

3. HOW TO TAKE FLUCOSTAT CAPSULE

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

ADULT

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	800 mg on the first day then 400 mg once daily

infections caused by <i>Candida</i>	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 once daily 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



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FLUCOSTAT 50 CAPSULE
FLUCOSTAT 150 CAPSULE
FLUCOSTAT 200 CAPSULE

Fluconazole 50mg, 150mg and 200mg Capsules

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 up 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 once daily (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 once daily
To stop cryptococcal meningitis from coming back	6 mg per kg of body weight once daily
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.

The 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.



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FLUCOSTAT 50 CAPSULE

FLUCOSTAT 150 CAPSULE

FLUCOSTAT 200 CAPSULE

Fluconazole 50mg, 150mg and 200mg Capsules

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 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

- 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 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)

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

Stop taking Fluconazole Capsules and seek medical attention immediately if you notice any of the following symptoms:

- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

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):

- 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):

- reduction in red blood cells which can make skin pale and cause weakness or breathlessness
- decreased appetite



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FLUCOSTAT 50 CAPSULE

FLUCOSTAT 150 CAPSULE

FLUCOSTAT 200 CAPSULE

Fluconazole 50mg, 150mg and 200mg Capsules

- 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):

- 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

Frequency not known, but may occur (cannot be estimated from the available data): • 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))

Reporting of side effects

If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

HOW TO STORE FLUCOSTAT CAPSULE

- Keep all medicines out of the reach of children.
- Store below 30°C
- Do not use FLUCOSTAT capsule after the expiry date 'EXP' which is stated on the carton and label. The expiry date refers to the last day of that month.

5. FURTHER INFORMATION

What Flucostat Capsules contains:

FLUCOSTAT 50 capsule contains 50mg of Fluconazole
 FLUCOSTAT 150 capsule contains 150mg of Fluconazole
 FLUCOSTAT 200 capsule contains 200mg of Fluconazole



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

FLUCOSTAT 50 CAPSULE
FLUCOSTAT 150 CAPSULE
FLUCOSTAT 200 CAPSULE

Fluconazole 50mg, 150mg and 200mg Capsules

What FLUCOSTAT CAPSULE looks like and contents of the pack

FLUCOSTAT 50, 150 and 200 capsules are packed as 1x10 and 10 X 10 capsules in an ALU-PVC placed in an inner carton with insert.

Supplier and Manufacturer

Fidson Healthcare Plc,
 Km.38, Lagos-Abeokuta Expressway,

Sango-Ota, Ogun State, Nigeria
234-(0)8077008888
customer@fidson.com