PACKAGE LEAFLET: INFORMATION FOR THE USER

# Fluconazole 50mg/5ml Powder for Oral Suspension

**(Fluconazole)**

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

**What is in this leaflet**


1. What Fluconazole 50mg/5ml Suspension is and what it is used for
2. What you need to know before you take Fluconazole 50mg/5ml Suspension
3. How to take Fluconazole 50mg/5ml Suspension
4. Possible side-effects
5. How to store Fluconazole 50mg/5ml Suspension
6. Contents of the pack and other information


## 1. WHAT FLUCONAZOLE 50MG/5ML SUSPENSION IS AND WHAT IT IS USED FOR

The name of this product is Fluconazole 50mg/5ml Powder for Oral Suspension.
It will be referred to as Fluconazole 50mg/5ml Suspension in this leaflet.
The active ingredient in Fluconazole 50mg/5ml Suspension is fluconazole.
Fluconazole belongs to a group of medicinal products 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 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 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 50MG/5ML SUSPENSION

**Do not take Fluconazole 50mg/5ml Suspension:**
- 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
- if you are taking astemizole, terfenadine (antihistamine medicines for allergies)
- if you are taking cisapride (used for stomach upsets)
- if you are taking pimozide (used for treating mental illness)
- if you are taking quinidine (used for treating heart arrhythmia)
- if you are taking erythromycin (an antibiotic for treating infections)

**Warnings and precautions**

**Talk to your doctor or pharmacist before taking Fluconazole 50mg/5ml Suspension:**
- if you have liver or kidney problems
- if you suffer from heart disease, including heart rhythm problems
- if you have abnormal levels of potassium, calcium or magnesium in your blood
- if you develop severe skin reactions (itching, reddening of the skin or difficulty in breathing)
- if you 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

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

**Other medicines and Fluconazole**

**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 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 (see section: "Do not take Fluconazole 50mg/5ml Suspension if you:")
There are some medicines that may interact with Fluconazole 50mg/5ml Suspension. Make sure your doctor knows if you are taking any of the following medicines as a dose adjustment or monitoring may be required to check that the medicines are still having the desired effect:
- rifampicin or rifabutin (antibiotics for infections)
- abrocitinib (used to treat atopic dermatitis, also known as atopic eczema)
- 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, triazopam 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 (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)
- 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 (alone or combined with other drugs used for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats 'arrhythmias').
- hydrochlorothiazide (a diuretic)
- ibrutinib (used for treating blood cancer)
- lurasidone (used to treat schizophrenia)

**Fluconazole 50mg/5ml Suspension with food and drink**

Fluconazole 50mg/5ml Suspension can be taken with or without food.

**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 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.
You can continue breast-feeding after taking a single dose of 150mg Fluconazole. You should not breast-feed if you are taking a repeated dose of Fluconazole.

**Driving and using machines**

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

**Fluconazole powder for oral suspension contains sucrose (sugar), sodium benzoate and sodium (salt)**
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product
- This drug contains 2.88g/5ml of sucrose. This should be taken into account in patients with diabetes mellitus
- May be harmful to teeth if used for periods longer than 2 weeks
- This medicine contains less than 1mmol sodium (23mg) per 5ml, that is to say essentially 'sodium-free'.

## 3. HOW TO TAKE FLUCONAZOLE 50MG/5ML SUSPENSION

Always take Fluconazole 50mg/5ml Suspension exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
It is best to take medicine at the same time each day.
The recommended doses of this medicine for different infections are below.

**Adults**

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 the 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 of mouth and 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
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 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).

*Please read the back of this leaflet.*

GENUS PHARMACEUTICALS

*Trademark

AP0973-10-1 92806452502 GB

**Children to 11 years old**
The maximum dose for children is 400 mg daily.
The dose will be based on child's weight in kilograms.
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 once daily. 6 mg per kg of body weight may 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 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 *Candida* (if their immune system is not working properly): 3 mg to 12 mg per kg of body weight once daily
**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.
**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.
**Instructions to make up the suspension:**
It is recommended that your pharmacist makes up Fluconazole powder for oral suspension before giving it to you.
**Instructions for use:**
Shake the closed bottle of the suspension every time before using. Turn the bottle upside down and tap it gently until all the powder moves freely. Add 23ml of water and shake vigorously. Shake again before use. A whitish suspension is obtained after its reconstitution with water. Dilution is not appropriate.
Every 5ml of reconstituted suspension will contain 50mg of fluconazole.
**If you take more Fluconazole 50mg/5ml Suspension than you should**
Taking too much Fluconazole may make you unwell. Contact your doctor or your nearest hospital casualty department at once. The symptoms of a possible overdose may include hearing, feeling or thinking things that are not real (hallucinations and paranoid behaviour). Symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.
**If you forget to take Fluconazole 50mg/5ml Suspension**
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, fluconazole can cause side effects, although not everybody gets them. Stop taking Fluconazole 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).

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 may 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 Fluconazole 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 (may affect up to 1 in 10 people) are:
- 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) are:
- reduction in red blood cells (anaemia) 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 (may affect up to 1 in 1,000 people) are:
- 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
- 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 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 doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme website: 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 50MG/5ML SUSPENSION

Keep this medicine out of the sight and reach of children.
Do not use Fluconazole 50mg/5ml Suspension after the expiry date which is stated on the bottle and the outer carton after EXP. The expiry date refers to the last day of that month. The unopened medicinal product does not require any special storage conditions. The suspension, once reconstituted, can be maintained at room temperature for a maximum period of 14 days, after which it must be disposed of. Do not store the reconstituted solution above 30°C. Do not freeze the reconstituted solution.
Medicines should not be disposed of via wastewater or household waste. Any remaining suspension should be discarded 14 days after reconstitution. 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 50mg/5ml Suspension contains**
The active ingredient is fluconazole. Every 5ml of suspension contains 50mg of fluconazole.
The other ingredients are: sucrose, citric acid monohydrate, sodium citrate anhydrous, sodium benzoate (E-211), xanthan gum, colloidal silica, titanium dioxide (E-171) and orange flavour (containing maltodextrin and arabic gum).
**What Fluconazole 50mg/5ml Suspension looks like and contents of the pack**
Fluconazole 50mg/5ml Suspension is presented as a powder for oral suspension, in a 35ml glass bottle with a polyethylene cap and seal. A dosing cup is included to measure 5 and 10ml. Pack sizes of 1 and 10 bottles (hospital use) are available. Not all pack sizes may be marketed.
**POM**
PL 06831/0220 Fluconazole 50mg/5ml Powder for Oral Suspension
**Marketing Authorisation Holder:**
Genus Pharmaceuticals, Linthwaite, Huddersfield, HD7 5QH, UK.
**Manufacturer:**
Neuraxpharm Pharmaceuticals, S.L.,
Avda. Barcelona 69, 08970 Sant Juan Despí, Barcelona, Spain.
**This leaflet was last revised in November 2024.**

GENUS PHARMACEUTICALS

*Trademark