

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.

- 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 any of the side-effects get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor.

What is in this leaflet

1. What Fluconazole 50mg/5ml Suspension is and what it is used for
2. 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 triazole antifungal drugs. These medicinal products are used for the treatment of a wide variety of infections caused by fungi.

Adults

You might be given this medicine by your doctor to treat the following types of fungal infections

- Systemic infections caused by Candida (candidiasis) and found in the blood stream, body organs (e.g. heart, lungs) or urinary tract
- Mucosal thrush (mucosal candidiasis) – infection affecting the lining of the mouth, throat and denture sore mouth
- Genital thrush – infection of the vagina or penis
- Cryptococcal meningitis – a fungal infection in the brain
- Skin infections (dermatomycosis) - e.g. athlete's foot, ringworm and jock itch (not including nail infections or ringworm infections of the hair/scalp).

You might also be given Fluconazole to:

- stop cryptococcal meningitis coming back (in patients with AIDS)
- stop you from getting a fungal infection (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

- Systemic infections caused by Candida (candidiasis) and found in the blood stream, body organs (e.g. heart, lungs) or urinary tract
- Mucosal thrush (mucosal candidiasis) – infection affecting the lining of the mouth, throat and denture sore mouth
- Cryptococcal meningitis – a fungal infection in the brain.

You might also be given Fluconazole to:

- stop you from getting a fungal infection (if your immune system is weak and not working properly).

2. BEFORE YOU TAKE FLUCONAZOLE 50MG/5ML SUSPENSION

Do not take Fluconazole 50mg/5ml Suspension:

- if you are allergic to fluconazole or other related compounds, or to any of the components of Fluconazole 50mg/5ml Suspension (listed in section 6). The symptoms may include itching, reddening of the skin or difficulty breathing
- if you are taking cisapride (a drug used for digestive problems / stomach upsets)
- if you are taking astemizole (a drug used for allergies)
- if you are taking terfenadine (a drug used for allergies) when administered with multiple doses of fluconazole of 400mg/day or higher
- if you are taking pimozide (a drug used for treating schizophrenia / mental illness)
- if you are taking quinidine (a drug that is used to treat irregular heartbeats / arrhythmia)
- if you are taking erythromycin (an antibiotic for treating infections)
- if you have a condition that affects the way your heart beats
- if you have heart disease
- if you have a slow heartbeat, irregular heartbeats
- if you are taking other medication that could affect your heartbeat in combination with fluconazole
- if you experience changes in the levels of sodium, calcium or magnesium in your blood.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluconazole 50mg/5ml Suspension:

- if you have liver or kidney problems
- 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 develop severe skin reactions (itching, reddening of the skin or difficulty in breathing)
- if you have an intolerance to sugars, as this product contains 2.88g of sucrose per 5ml.

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:")

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:

- terfenadine (used for allergies)
- rifampicin or rifabutin (antibiotics for infections inc. tuberculosis)
- 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, other coumarin oral anticoagulants or similar medicines)
- benzodiazepines (midazolam, lorazepam, oxazepam, lorazepam, 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)
- hydrochlorothiazide (a diuretic drug, i.e. it increases the amount of urine produced by the kidneys, used to treat hypertension).
- 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 and other HIV protease inhibitors (drugs for treating infection by HIV)
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- theophylline (used to control asthma)
- vitamin A (nutritional supplement)
- ivacaftor (used for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats 'arrhythmias').

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 or pharmacist for advice before taking this medicine.

Pregnancy

You must avoid the administration of low doses of fluconazole for short periods of time during pregnancy, except if you have a serious fungal infection and your doctor considers that the expected effect of the use of fluconazole may exceed the possible risks for the foetus. High doses or prolonged use of fluconazole is not recommended unless the infection is life threatening to the mother.

Breast-feeding

Fluconazole intake is not recommended during breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Fluconazole 50mg/5ml Suspension

- 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 a period longer than 2 weeks
- This product is essentially sodium free, i.e. it contains less than 23mg of sodium per 5ml.

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

Always take Fluconazole 50mg/5ml Suspension exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Your doctor will determine the dose depending on your weight and the type of infection. You must not take more than the amount specified by your doctor.

Your doctor will tell you the duration of your treatment with Fluconazole 50mg/5ml

Please read the back of this leaflet.



Suspension. Do not stop the treatment any sooner, even if you feel better. The reconstituted suspension of fluconazole is administered orally and may be taken with meals.

Adults

For treatment of infections of the vagina or penis: a single dose of 150mg.

For treatment of infections in the mouth, the dose is 50mg for 7-14 days. Treatment should not exceed 14 days in patients with underlying conditions.

For denture infections, 50mg should be given for 14 days alongside local anaesthetics.

For all other infections, the dosage is 50mg for 14 to 30 days. The dose may be increased to 100mg for persistent cases.

For skin infections, the dose is 50mg once daily for 2-4 weeks. Tinea pedis (athlete's foot) infections may require 6 weeks of treatment. The maximum period of treatment should not exceed 6 weeks.

For the treatment of invasive infections caused by fungi (systemic candidiasis), the usual dose is 400mg the first day followed by 200mg daily. Treatment duration is based on the patient's clinical response.

For the treatment of cryptococcal meningitis and other locations of infection by cryptococci, the usual dose is 400mg the first day, followed by 200-400mg once daily. The duration of treatment for cryptococcal infections will depend on the patient's response, but usually ranges between at least 6-8 weeks for cryptococcal meningitis.

For the prevention of cryptococcal meningitis relapses in patients with AIDS, once they have received a complete cycle of primary treatment, fluconazole may be administered indefinitely at a daily dose of 100-200mg.

To prevent fungal infections in patients treated with chemotherapy or radiotherapy, the dose may vary between 50 and 400mg depending on the patient's condition and the severity of the infection.

For patients at high risk of systemic infection, e.g. those undergoing a bone marrow transplant, the recommended dose is 400mg once daily. Fluconazole administration should start several days before the operation and continue for 7 days after the neutrophil count rises above 1000 cells per mm³.

Use in children and adolescents (from 28 days to 17 years)

As with infections in adults, treatment duration will be determined by your doctor.

Fluconazole will be administered in a single daily dose. The maximum daily dose for adults must not be exceeded in children.

Treatment of infections of the mouth: the dose should be 3mg/kg daily. An initial dose of 6mg/kg may be used.

Treatment of invasive infections of cryptococcal infections: the dose is 6-12mg/kg daily, depending on the severity of the disease.

To prevent fungal infections in patients treated with chemotherapy or radiotherapy, the dose may vary between 3 to 12mg/kg daily, depending on the patient's condition and the severity of the infection. A maximum dose of 400mg should not be exceeded.

Use of fluconazole in children for infections of the genitals is not recommended.

Use in children (from 0 to 28 days)

During the first 2 weeks of life, the same doses in mg/kg as for older children must be used, but administered every 72 hours. In children 3 and 4 weeks old, the dose must be administered every 48 hours. The maximum dosage of 12mg/kg in the stated periods should not be exceeded for this age group.

There are no studies on the use of fluconazole in children with kidney problems.

Fluconazole 50mg/5ml Suspension should only be given to children in hospital either orally or by intravenous injection. A suitable measuring device should be used and the suspension should not be diluted further.

The elderly

The normal doses should be administered when there are no signs of renal disturbance.

In patients with kidney disorders

In these patients (including children), the doctor must adjust the dose, reducing it according to your degree of renal disturbance. If you are subjected to renal dialysis, you must take the dose after every dialysis session.

Instructions for the correct administration of the preparation

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 prescribed

If you take more fluconazole than you have been told to, seek medical advice immediately.

If you forget to take Fluconazole 50mg/5ml Suspension

If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. In that case, skip the missed dose and take the next dose as normal. Do not take a double dose.

If you stop taking Fluconazole 50mg/5ml Suspension

Do not stop treatment early because your symptoms have improved. Your condition may not have been resolved and may reoccur if you do not finish your course of treatment.

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

4. POSSIBLE SIDE-EFFECTS

Like all medicines, fluconazole can cause side-effects, although not everybody gets them. The pattern and frequency of side-effects in children is expected to be similar to those seen in adults.

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.

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, shaking/tremors
- constipation, indigestion, 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.

Uncommon side effects (may affect up to 1 in 10,000 people) are:

- changes in renal function tests.

Other possible side effects (frequency cannot be estimated from the available data) are:

- Infection due to resistant microorganisms.

If any of the side-effects get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor.

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

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 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 carton. 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. 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 excipients 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.

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