

PACKAGE LEAFLET: INFORMATION FOR THE USER
Fluconazole 2mg/ml Solution for Infusion

Read all of this leaflet carefully before you start using 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 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, tell your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

Your medicine is called **Fluconazole 2mg/ml Solution for Infusion** (referred to as **Fluconazole Infusion** in this leaflet).

1. WHAT FLUCONAZOLE INFUSION IS AND WHAT IT IS USED FOR

Fluconazole Infusion is one of a group of medicines called antifungal agents. The active substance is fluconazole.

Fluconazole Infusion is used to treat infections caused by fungi and may also be used to stop you from getting candidal infections. 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 - infections affecting the lining of the mouth, throat and denture sore mouth

You might also be given fluconazole Infusion to:

- stop cryptococcal meningitis from coming back
- stop mucosal thrush from coming back
- 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 - infections 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 Infusion 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 ARE GIVEN FLUCONAZOLE INFUSION

You should not be treated with Fluconazole Infusion if you:

- are allergic 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 or 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 rhythm disorders)
- are taking erythromycin (an antibiotic for treating infections).

Warnings and precautions

Tell your doctor or nurse before you are given this medicine:

- 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 Fluconazol Infusion
- if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Fluconazol Infusion treatment. Stop taking Fluconazol Infusion and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Fluconazole Infusion:

Tell your doctor **immediately** if you are taking astemizole or terfenadine (antihistamines 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 Infusion (see section: “**You should not be treated with Fluconazole Infusion if you**”).

There are some medicines that may interact with Fluconazole Infusion. Make sure your doctor knows if you are taking any of the following medicines:

- rifampicin or rifabutin (antibiotics for infections)
- alfentanil, fentanyl (used as anaesthetics)
- amitriptyline, nortriptyline (used as anti-depressants)

- 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)
- 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)

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

Pregnancy, breast-feeding and fertility

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

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

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.

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

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

Driving and using machines

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

Fluconazole Infusion contains sodium

This medicine contains 177 mg sodium (main component of cooking/table salt) in each 50 ml bag. This is equivalent to 8.85 % of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 354 mg sodium (main component of cooking/table salt) in each 100 ml bag. This is equivalent to 17.7 % of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 708 mg sodium (main component of cooking/table salt) in each 200 ml bag. This is equivalent to 35.4 % of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need 110 ml or more Fluconazole Infusion daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. HOW FLUCONAZOLE INFUSION IS GIVEN

This medicine will be given by your doctor or nurse as a slow injection (infusion) into your vein.

Fluconazole Infusion is supplied as a solution. It will not be diluted further. There is more information for healthcare professionals in a section at the end of the leaflet.

The recommended doses of this medicine for different infections are below. Check with your doctor or nurse if you are not sure why you are being given Fluconazole Infusion.

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 <i>Candida</i>	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 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 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 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 bodyweight 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

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

If you have been given more Fluconazole Infusion than you should

If you are concerned that you may have been given too much Fluconazole Infusion, tell your doctor or nurse immediately. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucinations and paranoid behaviour).

If a dose of Fluconazole Infusion has been forgotten

As you will be given this medicine under close medical supervision, it is unlikely that a dose would be missed. However tell your doctor or pharmacist if you think that a dose has been forgotten.

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

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).

Fluconazole Infusion 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 Infusion and **tell your doctor immediately**.

Stop taking Fluconazole Infusion 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 (may affect up to 1 in 10 people):

- headache
- increases in blood tests of liver function
- rash
- stomach discomfort, diarrhoea, feeling sick, vomiting

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)
- shaking
- 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 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 doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly:

United Kingdom

Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Malta:

ADR Reporting website: www.medicinesauthority.gov.mt/adrportal.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FLUCONAZOLE INFUSION

Keep this medicine out of the sight and reach of children.

Store in the original container. Do not refrigerate or freeze. You should not be given unless the solution is clear and the container undamaged. The doctor or nurse will check that the expiry date on the label has not passed.

You should not be given this medicine after the expiry date which is stated on the carton and label. Once open, the infusion will be used immediately and any unused solution will be thrown away.

Do not throw away any medicines via wastewater or household waste.

These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Fluconazole Infusion contains**

The active ingredient is fluconazole 2mg/ml.

The other ingredients are sodium chloride, sodium hydroxide and water for injections.

What Fluconazole Infusion looks like and the contents of the pack

Your medicine is a clear solution in a plastic infusion bag, inside a polyester/ aluminium/ polypropylene overbag.

Each 50ml, 100ml and 200ml infusion bag contains 100mg, 200mg and 400mg fluconazole respectively.

Marketing Authorisation Holder:

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2540 Luxembourg

Manufacturer:

Infomed Fluids SRL
50 Theodor Pallady Blvd
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INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for medical or healthcare professionals only.

Intravenous infusion should be infused at a rate not exceeding 10 ml/minute.

The solution for infusion is for single use only. Discard any remaining solution.

In the absence of compatibility studies, this medicinal product should not be mixed with other medicinal products.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.