

# Fluconazole 2 mg/ml

## solution for infusion

fluconazole

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

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

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

Fluconazole is used to treat infections caused by fungi and may also be used to stop you from getting 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

You might also be given Fluconazole 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 - 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

#### Do not take Fluconazole:

- 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.
- if you are taking astemizole, terfenadine (antihistamine medicines for allergies).
- if you are taking cisapride (used for stomach upsets).
- if you are taking pimoziide (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 nurse before taking Fluconazole 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.
- 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 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.

#### Other medicines and Fluconazole

Tell your doctor immediately if you are taking astemizole, terfenadine (an antihistamine for treating allergies) or cisapride (used for stomach upsets) or pimoziide (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 if you”).

There are some medicines that may interact with Fluconazole. 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 and losartan (for hypertension- high blood pressure)
- 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)
- vitamin A (nutritional supplement)
- ivacaftor (used for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats ‘arrhythmias’)
- hydrochlorothiazide (a diuretic)

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

You should not take Fluconazole 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 Fluconazole up to 200 mg.

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 contains 3.54 mg sodium per ml solution. To be taken into consideration by patients on a controlled sodium diet.

Make sure you tell your doctor or pharmacist if you are on a sodium restricted diet before taking fluconazole.

### 3. HOW TO TAKE FLUCONAZOLE

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

#### 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 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	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).



The following information is intended for healthcare professionals only:

## Fluconazole 2 mg/ml

### Solution for infusion

fluconazole

#### 1. Administration

For intravenous use as infusion only.

Fluconazole is dissolved in isotonic saline solution, with an electrolyte content of Na<sup>+</sup> 150 mmol and Cl<sup>-</sup> 150 mmol per 1000 ml, and may be administered directly as an infusion. The infusion rate should not exceed 20 mg (10 ml)/minute for adults. For children, it is recommended that the infusion rate not exceed 10 mg (5 ml)/min. For premature infants the infusion time should be no less than 15 minutes. In patients requiring sodium- or fluid restriction, the rate of administration should be taken into consideration as Fluconazole consists of a salt solution. In such cases the infusion should be given over a longer period.

#### 2. Handling Instructions

Fluconazole intravenous infusion is compatible with the following administration fluids:

- Dextrose 20% solution
- Ringer’s solution
- Ringer’s-lactate solution
- Potassium chloride 1% in 5% dextrose solution
- Sodium bicarbonate 4.2% solution
- Sodium chloride 9 mg/ml (0,9%) solution

Fluconazole may be infused through an existing line with one of the above listed fluids. Although no specific incompatibilities have been noted, mixing with any other medicinal products prior to infusion is not recommended.

The solution for infusion is for single use only.

## 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 (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
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

## 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 take more Fluconazole than you should

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

## If you forget to take Fluconazole

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, pharmacist 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 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 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 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 and **tell your doctor immediately**.

## 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).

## 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
- 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



From a microbiological point of view, the dilutions should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

The dilution is to be made under aseptic conditions. The solution is to be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

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

## Handling glass vials:

Fluconazole 2 mg/ml may be infused via a suitable cannula directly or diluted with any of the fluids in the list above.

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)
- 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

## 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 national reporting system listed in Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://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

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

Do not use this medicine after the expiry date which is stated on the pack after EXP.

The expiry date refers to the last day of that month.

Storage conditions:

Do not freeze.

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

This leaflet does not contain all the information about this medicine. If you have any questions or are not sure about anything, ask your doctor.

## What Fluconazole contains

The active substance is fluconazole.

1 ml solution for infusion contains 2 mg of fluconazole.  
50 ml/100 ml of infusion vial contains 100 mg/200 mg of fluconazole.  
200 ml of infusion bags contains 400 mg of fluconazole.

## The other ingredients are:

- water for injections
- sodium chloride
- hydrochloric acid for pH-adjustment

## What Fluconazole looks like and contents of the pack

Solution for infusion.

The solution in the vial/plastic bag is clear and colourless.

This medicine is available in:

- a vial containing a total of either 100 mg or 200 mg fluconazole in pack sizes of 1, 5 or 10.
- a bag containing a total of 400 mg fluconazole in pack size of 1 or 10 bags.

Not all pack sizes may be marketed.

## Marketing Authorisation Holder and Manufacturer:

Hikma Farmacêutica (Portugal) S.A.  
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## This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Fluconazol Hikma 2 mg/ml Infusionslösung  
Germany: Fluconazol Hikma 2 mg/ml Lösung zur Infusion  
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