

# 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 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).
- if you are taking amiodarone (used for treating uneven heartbeats ‘arrhythmias’).

#### 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).

#### 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 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 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’)

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 while you are pregnant unless your doctor has told you to.

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



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.

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.

### 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 (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**.

### 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 10 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 side effects (may affect up to 1 in 10 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).

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 bag or 10 bags.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer:

Hikma Farmacêutica (Portugal) S.A.  
Estrada do Rio da Mó n. 8, 8A e 8B  
Fervença  
2705-906 Terrugem SNT  
Portugal

### Distributed by:

Consilient Health (UK) Ltd.  
No.1 Church Road,  
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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  
Italy: Fluconazolo Hikma 2 mg/ml Soluzione per infusione  
Netherlands: Fluconazol Hikma 2 mg/ml oplossing voor intraveuze infusie

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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.

### Handling plastic bags:

Do not remove unit from overwrap until ready for use. The overwrap is a moisture barrier. The inner bag maintains the sterility of the product.

**To open**, tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. After removing overwrap, check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired.

**CAUTION:** Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.