

# Fluconazole

2mg/ml Solution for Infusion

## PATIENT INFORMATION LEAFLET

Fluconazole 100 mg/50 ml

Fluconazole 200 mg/100 ml

### 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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### In this leaflet

1. What is Fluconazole Solution for Infusion and what is it used for?
2. Before you take Fluconazole Solution for Infusion
3. How to take Fluconazole Solution for Infusion
4. Possible side effects
5. Storing Fluconazole Solution for Infusion
6. Further information

## 1. WHAT FLUCONAZOLE SOLUTION FOR INFUSION IS AND WHAT IS IT USED FOR?

Each ml of solution contains 2 mg fluconazole, which is the active substance. The solution also contains the following inactive ingredients: Water for injections and 0.9% sodium chloride (the 100 mg / 50 ml vial contains 7.7 mmol sodium and the 200 mg / 100 ml vial contains 15.4 mmol sodium). Hydrochloric acid is used to adjust the acidity of the injection.

Fluconazole Solution for Infusion is available in two pack sizes: 100 mg / 50 ml and 200 mg / 100 ml.

Fluconazole Solution for Infusion belongs to a group of medicines called anti-fungal agents.

Fluconazole Solution for Infusion is used to treat infections caused by fungi/yeasts. It may also be used to stop you from getting a fungal infection. The most common cause of fungal infections is a yeast called *Candida*.

You may be given Fluconazole Solution for Infusion by your doctor to treat fungal infections such as:

- Thrush of the mouth or throat (mucosal infections). Thrush is commonly caused by *Candida*.
- Skin infections e.g. athlete's foot, ring worm.
- Internal (systemic) fungal infections caused by *Candida*, e.g. infections of the blood stream, urinary tract or other body organs.
- Internal (systemic) fungal infections caused by *Cryptococcus*, e.g. cryptococcal meningitis and infections of other sites such as the lungs and skin.
- Genital *Candida* infections, e.g. vaginal thrush or candidal balanitis (inflammation of the end of the penis and/or foreskin).

### You may also be given Fluconazole Solution for Infusion to:

- Stop you from getting a fungal infection (if your immune system is not working properly).
- Stop an infection caused by *Cryptococcus* from coming back (in AIDS patients).

## 2. BEFORE YOU TAKE FLUCONAZOLE SOLUTION FOR INFUSION

Tell your doctor **immediately** if your answer is **YES** to any of following situations:

- You are pregnant or trying to become pregnant.
- You are breast-feeding.
- You have liver or kidney problems.
- You ever have had an allergic reaction to any of the ingredients of Fluconazole Solution for Infusion or other medicines, which you may have taken to treat a fungal infection. This may have been itching, reddening of the skin or difficulty in breathing.
- You are taking either terfenadine (an antihistamine) or cisapride (used for stomach upsets).
- You have ever had any form of cancer.
- You have AIDS.
- You are on a low-sodium diet. Your medicine contains the following amounts of sodium and may not be suitable for you:

Fluconazole 100 mg / 50 ml Solution for Infusion: 7.7 mmol sodium

Fluconazole 200 mg / 100 ml Solution for Infusion: 15.4 mmol sodium

Inform your doctor if you are taking any of the following medicines:

- Warfarin or coumarin drugs (to prevent blood clots).
- Oral sulphonylureas such as chlorpropamide, glibenclamide, glipizide or tolbutamide (to control diabetes).
- Diuretics, such as hydrochlorothiazide, used to treat fluid retention and high blood pressure.
- Benzodiazepines (used as tranquilizers).
- Phenytoin (used to control epilepsy).
- Rifampicin or rifabutin (antibiotics).
- Ciclosporin or tacrolimus (used to affect the immune response).
- Theophylline (used to control asthma).
- Astemizole (an antihistamine).
- Zidovudine, also known as AZT (used in HIV-infected patients).

Tell your doctor of any medicines you are taking including those that were not prescribed for you that you may have bought.

## 3. HOW TO TAKE FLUCONAZOLE SOLUTION FOR INFUSION

This medicine is normally given in hospital by your doctor or nurse as an intravenous infusion over approximately 30 minutes.

Fluconazole Solution for Infusion is supplied as solution. It is unnecessary to dilute it further.

This medicine should not be mixed with any other drug before infusion.

Your first dose will depend on the type and severity of your infection, your age, weight and kidney function.

Check with your doctor or nurse if you are not sure why you are being given Fluconazole Solution for Infusion.

The usual doses of Fluconazole Solution for Infusion for different infections are below:

## Adults

Mucosal infections of mouth	50-100 mg once daily for 7-14 days
Mucosal infections of throat or elsewhere	50-100 mg once daily for 14-30 days
Fungal skin infections	50mg once daily for 2-4 weeks. Athlete's foot may need up to 6 weeks treatment
Internal fungal infections caused by <i>Candida</i>	400 mg on the first day then 200-400 mg once daily
Internal fungal infections caused by <i>Cryptococcus</i>	400 mg on the first day then 200-400 mg once daily for 6-8 weeks
To stop you from getting a fungal infection	50-400 mg once daily while you are at risk of getting an infection
To prevent a cryptococcal infection from coming back	100-200 mg once daily indefinitely
To treat genital <i>Candida</i> infection	150 mg as a single dose

## Children

<b>4 weeks to 15 years old</b>	
Mucosal infections	3 mg/kg once daily.
Internal fungal infections caused by <i>Candida</i> or <i>Cryptococcus</i>	6-12 mg/kg once daily.
Prevention of fungal infections	3-12 mg/kg once daily while at risk of getting an infection.
<b>2-4 weeks old</b>	
Same dose as above but given once every 2 days. A maximum dose of 12 mg/kg every 2 days.	
<b>Less than 2 weeks old</b>	
Same dose as above but given once every 3 days. A maximum dose of 12 mg/kg every 3 days.	
A maximum dosage of 400 mg daily should not be exceeded in children.	
Use of Fluconazole Solution for Infusion for treating genital <i>Candida</i> infections in children under 16 years old is not recommended.	

## Elderly

The usual adult dose should be given unless you have kidney problems.

## Patients with kidney problems

Your doctor may modify your dose, depending on your kidney function. Doctors sometimes prescribe different doses to those listed above. If your kidneys are not working properly you may be given a different dose. Ask your doctor or nurse if you want to know what doses you are being given.

If you have the impression that the effect of Fluconazole Solution for Infusion is too strong or too weak, talk to your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Fluconazole Solution for Infusion can have side effects.

The most common undesirable effects are:

- Nausea
- Stomach discomfort

- Diarrhoea
- Wind (flatulence)
- Rash
- Headache

The following have occurred rarely in patients being given this medicine but they may not all be due to the drug:

- Itching
- Vomiting
- Seizure
- Abnormalities in blood/liver function/urine or other biochemical tests
- Liver toxicity
- Severe skin reactions
- Hair loss
- Dizziness
- Swelling of the face
- Altered sense of taste

A few people develop allergic reactions to medicines. If you develop any of the following undesirable effects tell your doctor or nurse **immediately**:

- Sudden wheeziness, difficulty in breathing or tightness in chest
- Swelling of eyelids, face, lips or blood vessels under the skin
- Severe rash, skin lumps or itchy red spots
- Itch all over body

AIDS patients should be warned that they are likely to be prone to skin reactions to many drugs, including Fluconazole Solution for Infusion.

Tell your doctor or nurse if you become unwell or have any other discomfort you do not understand.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## 5. STORING FLUCONAZOLE SOLUTION FOR INFUSION

Keep out of the reach and sight of children.

Store below 30°C (unopened packaging). The solution for infusion should not be frozen.

The doctor or nurse will check that the expiry date on the label has not passed.

Once open, any unused infusion will be discarded, since the solution contains no preservatives.

## 6. FURTHER 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 or nurse.

For any information about this medicinal product, please contact the Marketing Authorisation Holder / Manufacturer or its local representative:

**Marketing Authorisation Holder**  
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