

Patient Information Leaflet (UK)
Fluconazole 2mg/ml Infusion

Please read this leaflet carefully.

This leaflet tells you about Fluconazole 2 mg/ml Infusion. If you do not understand or you want to know more, ask your doctor, nurse or pharmacist. Keep this leaflet; you may want to read it again.
The name of this medicine is Fluconazole 2 mg/ml Infusion. The active ingredient is fluconazole.

What is in your medicine?

Fluconazole 2 mg/ml Infusion contains the Active Ingredient Fluconazole 2 mg per ml of solution.
Inactive ingredients: Sodium Chloride (900 mg/100 ml), Water For Injections (q.s.) (Sodium 15.4 mmol/100 ml)
Fluconazole 2 mg/ml Infusion comes in a glass bottle containing a total of 200 mg Fluconazole.

Marketing Authorisation Holder:

Claris Lifesciences (UK) Limited, Crewe Hall, Crewe, United Kingdom.

Manufacturer:

Claris Lifesciences Limited, Corporate Towers, Near Parimal Railway Crossing, Ellisbridge, Ahmedabad - 380 006,
At: Chacharwadi-Vasana, Ahmedabad - 382 213, Gujarat, India.

Before you are given Fluconazole 2mg/ml Infusion

If the answer is **YES** to any of these questions - tell your doctor immediately

- Do you suffer from heart disease including rhythm problems?
- Are you pregnant or trying to become pregnant?
- Are you breast-feeding?
- Do you have liver or kidney problems?
- Have you ever had an allergic reaction to any of the ingredients of Fluconazole 2mg/ml 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.
- Are you taking either terfenadine (an antihistamine) or cisapride (used for stomach upsets)?
- If you are on a controlled Sodium diet or require Sodium or fluid restriction, the consideration should be given to the salt content of the infusion fluid (15.4 mmol/100 ml of Sodium) and the total volume of fluid administered.

What type of medicine is Fluconazole 2mg/ml Infusion?

Fluconazole is one of a group of medicines called anti-fungal agents.

What is your medicine for?

Fluconazole 2mg/ml 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 yeast called *Candida*.

You may be given Fluconazole 2mg/ml 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, ringworm.
- 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 like vaginal thrush or candidal balanitis (inflammation of the end of the penis and/or foreskin).

You may also be given Fluconazole 2mg/ml 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).

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 tranquillizers)
- 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.

Doses of Fluconazole 2mg/ml Infusion

This medicine is given by your doctor, nurse or pharmacist as an intravenous infusion over approximately 30 minutes.

Fluconazole 2 mg/ml Infusion is supplied as a solution. It is unnecessary to dilute it further.
This medicine should not be mixed with any other drug before infusion.
The usual doses of Fluconazole 2 mg/ml Infusion for different infections are below. Check with your doctor, nurse or pharmacist if you are not sure why you are being given Fluconazole 2 mg/ml Infusion.

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

4 weeks to 15 years old	Mucosal infections Internal fungal infections caused by <i>Candida</i> or <i>Cryptococcus</i>	3 mg/kg once daily. 6-12 mg/kg once daily.
2-4 weeks old	Prevention of fungal infections	3-12 mg/kg once daily while at risk of getting an infection.
Less than 2 weeks old	Same dose as above but given once every 2 days. A maximum dose of 12 mg/kg every 2 days. 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 2 mg/ml Infusion for treating genital *Candida* 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 these. If your kidneys are not working properly you may be given a different dose. Ask your doctor, nurse or pharmacist if you want to know what doses you are being given.

Does your medicine cause undesirable effects?

Fluconazole 2mg/ml Infusion may cause some undesirable effects. The most common undesirable effects are:
• nausea • stomach discomfort • diarrhoea • wind • rash • headache
The following have occurred rarely in patients being given this medicine but they may not all be due to the drug.
• change in heart rate or rhythm • 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, nurse or pharmacist **immediately**:
• sudden wheeziness, difficulty in breathing or tightness in chest • swelling of eyelids, face or lips • 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 2 mg/ml Infusion.
Tell your doctor, nurse or pharmacist if you become unwell or have any other discomfort you do not understand.

Storage

The infusion will be stored in the outer carton to protect from light, below 25°C before it is used. The infusion should not be frozen. The doctor, nurse or pharmacist will check that the expiry date on the label has not passed. Once open any unused infusion will be discarded.

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, nurse or pharmacist.
The information in this leaflet is about Fluconazole 2 mg/ml Infusion only.
Keep all medicines out of the reach and sight of children.

Date of Issue of this leaflet for Fluconazole 2 mg/ml Infusion, United Kingdom is 15 / 11 / 2005

Manufactured by :
Claris Lifesciences Limited
Chacharwadi-Vasana,
Ahmedabad-382 213, India.

Marketing Authorisation Holder :
Claris Lifesciences UK Limited
Crewe Hall, Crewe, Cheshire,
CW1 6UL, United Kingdom.

EEC/Fluconazole(05)-UK-PIL