

Package leaflet: Information for the user

Mycozal 2 mg/ml Solution for Infusion Fluconazole

Read all of this leaflet carefully before you are given 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 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 Mycozal 2mg/ml Solution for Infusion is and what it is used for
2. What you need to know before you are given Mycozal Infusion
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1. What Mycozal 2mg/ml Solution for Infusion is and what it is used for

Mycozal is one of a group of medicines called “antifungals”. The active substance is fluconazole. Mycozal is used to treat infections caused by fungi and may also be used to stop you from getting a 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 Mycozal 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 Mycozal 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 Mycozal Infusion

Do not use Mycozal Infusion if you

- are allergic to fluconazole or 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, 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 arrhythmia)
- are taking erythromycin (an antibiotic for treating infections)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Mycozal Infusion.

Tell your doctor, pharmacist or nurse if you

- have liver or kidney problems
- suffer from heart disease, including heart rhythm problems
- have abnormal levels of potassium, calcium or magnesium in your blood.
- develop severe skin reactions (itching, reddening of the skin or difficulty in breathing).
- 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 Mycozal Infusion

Tell your doctor or pharmacist if you are taking, have recently taken or you might take astemizole, terfenadine (an antihistamine for treating allergies) or cisapride (used for stomach upsets) or pimozone (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 Mycozal (see section: “Do not use Mycozal if you”).

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

- amiodarone (used for treating uneven heartbeats ‘arrhythmias’)
- hydrochlorothiazide (a diuretic)
- 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)

Please tell your doctor or pharmacist if you are taking or have recently taken 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 are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take Mycozal Infusion while you are pregnant unless your doctor has told you to. You can continue breast-feeding after taking a single dose of Mycozal Infusion up to 200 mg. You should not breast-feed if you are taking a repeated dose of Mycozal Infusion.

Driving and using machines

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

Mycozal Infusion contains sodium

Mycozal Infusion contains 3.5mg of sodium per ml of infusion. If you are on a low sodium (salt) diet tell your doctor or nurse before they give you Mycozal Infusion.

3. How Mycozal Infusion is given

This medicine will be given by your doctor or nurse as a slow injection (infusion) into your vein. Mycozal 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 Mycozal 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	200 mg to 400 mg on the first day

of mouth, throat and denture sore mouth	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).

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 recommended adult dose will be given unless you have kidney problems.

Patients with kidney problems

Your doctor may change your dose depending on your kidney function.

If you receive more Mycozal Infusion than you should

If you are concerned that you may have been given too much Mycozal 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 (hallucination and paranoid behaviour).

If a dose of Mycozal 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, 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).

Mycozal 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 Mycozal Infusion 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) are:

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

Uncommon side effects (may affect up to 1 in 100 people) are:

- 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 1,000 people) are:

- 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

Pharmaceutical Services

Ministry of Health

CY-1475 Nicosia

Fax: + 357 22608649

Website: www.moh.gov.cy/phs

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

5. How to store Mycozal Infusion

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 carton or bottle after EXP. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

After first opening:

From the microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not throw away any medicines via wastewater or household waste. Any unused solution should be returned to the pharmacy for disposal. These measures will help protect the environment.

6. Contents of the pack and other information

What Mycozal Infusion contains

The active substance is Fluconazole.

Each ml of infusion contains 2mg fluconazole.

Each 25ml bottle of Mycozal Infusion contains 50mg of fluconazole.

Each 50ml bottle of Mycozal Infusion contains 100mg of fluconazole.

Each 100ml bottle of Mycozal Infusion contains 200mg of fluconazole.

Each 200ml bottle of Mycozal Infusion contains 400mg of fluconazole.

The other ingredients are: sodium chloride, water for injections, hydrochloric acid for pH adjustment and sodium hydroxide for pH adjustment.

What Mycozal Infusion looks like and contents of the pack

Fluconazole Infusion is a clear sterile and colourless solution for infusion. The infusion is supplied in a glass bottle closed with a rubber stopper and a flip-off aluminium cap.

Fluconazole Infusion is available in a bottle containing 25ml, 50ml, 100ml or 200ml of solution for infusion. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sapiens Pharmaceuticals Ltd
Ierou Lochou 39, Kapsalos 3082,
Limassol, Cyprus

Manufacturer

Pharmathen S.A., 6 Dervenakion str, 15344 Pallini, Attiki, Greece
or

ANFARM HELLAS S.A. Sximatari Viotias, Sximatari Viotias 32009, Greece

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

This medicinal product is authorised in the Member States of the EEA under the following names:

Cyprus: Mycozal 2 mg/ml Solution for Infusion

Germany: Fluconazol-GRY 2 mg/ml Infusionslösung

Greece: Stabilanol 2 mg/ml Solution for Infusion

Netherlands: Fluconazol Novopharm 2 mg/ml Solution for Infusion

This leaflet was last revised in.

The following information is intended for healthcare professionals only:

1. Administration

For intravenous use as infusion.

Fluconazole is dissolved in an isotonic saline solution, with an electrolyte content of 150 mmol Na⁺ and 150 mmol Cl⁻ per 1000 ml, and may be administered directly as an infusion. The product can be infused at a maximum rate of 10ml/minute. In children the rate of intravenous infusion should not exceed 5ml/minute. 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

For single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

The product should be inspected visually for particles and discoloration prior to administration. Only clear and colourless solutions should be used.

Mycozal 2mg/ml solution for infusion is compatible with the following infusion fluids:

- a. glucose 20%
- b. Ringer's solution
- c. Hartmann's solution
- d. Potassium chloride in glucose
- e. sodium carbonate 4.2%
- f. 0.9% sodium chloride (isotonic saline)

Compatibility has been shown for short duration (10 minutes).

Dilution of Mycozal 2mg/ml solution for infusion is not required prior to administration. If necessary, Fluconazole and the solutions mentioned above should be administered through separate infusion containers. The two reservoirs should be connected using a "Y" connection. The two solutions are then mixed in a single line and the administration is performed. The above method is recommended in order to avoid effects such as the "layering effect" if the two solutions were mixed in one infusion container for the total period of the administration.

3. Storage information

Do not use after the expiry date stated on the carton or bottle. The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

After first opening

From the microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately.

If not used immediately, in-use storage times and conditions are the responsibility of the user.