

Flucol 2 mg/ml Solution for Infusion, 100 ml

Fluconazole

Read all of this leaflet carefully before you start taking 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.

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Contents of the pack and other information



Flucol 2 mg/ml is one of a group of medicines called “antifungals”. The active substance is fluconazole.

Flucol 2 mg/ml 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 Flucol 2 mg/ml 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 Flucol 2 mg/ml 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

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What you need to know before you are given Flucol 2 mg/ml

You should not be treated with Flucol 2 mg/ml 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.
- 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 before you are given Flucol 2 mg/ml 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)

Other medicines and Flucol 2 mg/ml

Tell your doctor **immediately** if you are taking astemizole, terfenadine (antihistamines 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 Flucol 2 mg/ml (see section: “Do not take Flucol 2 mg/ml if you”).

There are some medicines that may interact with Flucol 2 mg/ml. 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)

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

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 receiving this medicine.

Your doctor will decide whether you should be given Flucol 2 mg/ml.

Driving and using machines

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

Flucol 2 mg/ml contains sodium

Flucol 2 mg/ml contains 0.154 mmol sodium per ml. To be taken into consideration by patients on a controlled sodium diet.

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How Flucol 2 mg/ml is given

This medicine will be given by your doctor or nurse as a slow injection (infusion) into your vein. Flucol 2 mg/ml 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 usual 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 Flucol 2 mg/ml.

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).

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.

Doctors sometimes prescribe different doses to these. Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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 receive more Flucol 2 mg/ml than you should

If you are concerned that you may have been given too much Flucol 2 mg/ml, 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 Flucol 2 mg/ml 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 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)

Flucol 2 mg/ml 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 Flucol 2 mg/ml and **tell your doctor immediately**.

Other side effects:

Common side effects which affect 1 to 10 users in 100 are listed below:

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

Uncommon side effects which affect 1 to 10 users in 1,000 are listed below:

- 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 which affect 1 to 10 users in 10,000 are listed below:

- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Flucol 2 mg/ml

- 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 and the label of the vial after “EXP”. The expiry date refers to the last day of that month.
- Do not refrigerate or freeze.
- Only clear solutions practically free from particles should be used.
- This medicinal product is for single use. Once opened, any unused infusion should be discarded.
- For storage conditions of the reconstituted product see end of this leaflet.

Do not throw away any medicines via wastewater. 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

What Flucol 2 mg/ml contains

- The active substance is fluconazole.
- Each ml contains 2 mg of fluconazole.
- The other ingredients are: sodium chloride, hydrochloric acid 25% (for pH adjustment), water for injections.

What Flucol 2 mg/ml looks like and contents of the pack

- Flucol 2 mg/ml is a clear, colourless solution with no visible particles.
- It comes in 1, 5, 7, 14 and 20 glass vials containing a total of 100 mg (50 ml), 200 mg (100 ml), 400 mg (200 ml) fluconazole.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers:

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

Az. Chim. Riun. Angelini Francesco ACRAF SPA, Via Vecchia Del Pinocchio, 22, 60100 – Ancona, Italy.

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

Austria	FLUCONAZOL SANDOZ 2 mg/ml - Infusionslösung
Germany	Fluconazol HEXAL 2 mg/ml Infusionslösung
Ireland	Flucol 2 mg/ml Solution for Infusion, 100 ml
Italy	Fluconazolo Angelini 2 mg/ml soluzione per infusione endovenosa
Luxembourg	Fluconazol HEXAL 2 mg/ml Infusionslösung
Netherlands	Fluconazol Sandoz infuus 200 mg/100 ml, oplossing voor intraveneuze infusie 2 mg/ml
Sweden	FLUCONAZOL HEXAL
United Kingdom	Fluconazole 2 mg/ml solution for infusion

This leaflet was last revised in 01/2016.

The following information is intended for healthcare professionals only:

Intravenous infusion should be administrated at a rate not exceeding 10 ml/minute. Flucol 2 mg/ml is formulated in sodium chloride 9 mg/ml (0.9%) solution for infusion, each 200 mg (100 ml bottle) containing 15 mmol each of (Na⁺) and Cl⁻. Because Flucol 2 mg/ml is available as a dilute sodium chloride solution, in patients requiring sodium or fluid restriction, consideration should be given to the rate of fluid administration.

Fluconazole intravenous infusion is compatible with the following administration fluids:

- a) Dextrose 20%
- b) Ringer’s solution
- c) Hartmann’s solution
- d) Potassium chloride in dextrose
- e) Sodium bicarbonate 4.2%
- f) Sodium chloride 9 mg/ml (0.9%)

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.

Chemical and physical in-use stability has been demonstrated for 48 hours at room temperature in each of the infusion solutions listed above.

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.

In case of Ringer’s solution, storage below 25°C is recommended. Dilutions with Ringer’s solution should not be refrigerated.

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 .

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