

Package leaflet: Information for the user

Diflucan® 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 Diflucan is and what it is used for
2. What you need to know before you take Diflucan
3. How to take Diflucan
4. Possible side effects
5. How to store Diflucan
6. Contents of the pack and other information

1. What Diflucan is and what it is used for

Diflucan is one of a group of medicines called “antifungals”. The active substance is fluconazole.

Diflucan 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 Diflucan 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 Diflucan 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 Diflucan

Do not take Diflucan

- 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)

Warnings and precautions

Talk to your doctor or nurse before taking Diflucan

- if you 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)
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking fluconazole

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with fluconazole treatment. Stop taking Diflucan and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Talk to your doctor or pharmacist if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Other medicines and Diflucan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 Diflucan (see section: "Do not take Diflucan if you").

There are some medicines that may interact with Diflucan. Make sure your doctor knows if you are taking any of the following medicines as a dose adjustment or monitoring may be required to check that the medicines are still having the desired effect:

- rifampicin or rifabutin (antibiotics for infections)
- abrocitinib (used to treat atopic dermatitis, also known as atopic eczema)
- 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, verapamil, felodipine and losartan (for hypertension - high blood pressure)
- olaparib (used for treating ovarian cancer)
- 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)
- tofacitinib (used for treating rheumatoid arthritis)
- tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline
- vitamin A (nutritional supplement)
- ivacaftor (alone or combined with other drugs used for treating cystic fibrosis)
- amiodarone (used for treating uneven heartbeats ‘arrhythmias’)
- hydrochlorothiazide (a diuretic)
- ibrutinib (used for treating blood cancer)
- lurasidone (used to treat schizophrenia)

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.

If you are planning to become pregnant, it is recommended to wait a week after a single dose of fluconazole before becoming pregnant.

For longer courses of treatment with fluconazole, talk to your doctor on the need for appropriate contraception during treatment which should continue for one week after the last dose.

You should not take Diflucan if you are pregnant, think you may be pregnant, are trying to become pregnant, unless your doctor has told you so. If you become pregnant while taking this medicine or within 1 week of the most recent dose, contact your doctor.

Fluconazole taken during the first or second trimester of pregnancy may increase the risk of miscarriage. Fluconazole taken during the first trimester may increase the risk of a baby being born with birth defects affecting the heart, bones and/or muscles.

There have been reports of babies born with birth defects affecting the skull, ears, and bones of the thigh and elbow in women treated for three months or more with high doses (400-800 mg daily) of fluconazole for coccidioidomycosis. The link between fluconazole and these cases is not clear.

You can continue breast-feeding after taking a single dose of 150 mg Diflucan.

You should not breast-feed if you are taking a repeated dose of Diflucan.

Driving and using machines

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

Diflucan contains sodium (salt)

Diflucan contains 88.5 mg sodium (main component of cooking/table salt) per 25 ml. This is equivalent to 4.4% of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your pharmacist or doctor if you need Diflucan on a daily basis for a prolonged period of time, especially if you have been advised to have a low salt diet.

3. How to take Diflucan

This medicine will be given by your doctor or nurse as a slow injection (infusion) into your vein. Diflucan 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 Diflucan.

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 once daily 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 from coming back	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 once daily (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 once daily
To stop cryptococcal meningitis from coming back	6 mg per kg of body weight once daily
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 once daily

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 Diflucan than you should

If you are concerned that you may have been given too much Diflucan, 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 Diflucan

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.

Stop taking Diflucan and seek medical attention **immediately** if you notice any of the following symptoms:

- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)

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).

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

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)
- low blood potassium
- shaking
- 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

Frequency not known, but may occur (cannot be estimated from the available data):

- hypersensitivity reaction with skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (Drug Reaction or rash with Eosinophilia and Systemic Symptoms (DRESS))

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 Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diflucan

- 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.
 - Once opened the product should be used immediately. Any unused infusion should be discarded. This medicinal product is for single use only.
 - Do not use this medicine if you notice visible particles or if the solution is unclear or discoloured.

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

What Diflucan contains

- The active substance is fluconazole.
- Each ml contains 2 mg of fluconazole.
1 vial with 100 ml solution for infusion contains 200 mg fluconazole.

- The other ingredients are sodium chloride and water for injections (see section 2, Diflucan contains sodium (salt)).

What Diflucan looks like and contents of the pack

- Diflucan is a clear, colourless solution with no visible particles.
- It comes in glass vials.

Pack sizes:

- 1, 40 vial(s) containing 100 ml solution for infusion
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pfizer Healthcare Ireland Unlimited Company
The Watermarque Building
Ringsend Road,
Dublin 4,

D04 K7N3
Ireland

Manufacturer

Fareva Amboise
Zone Industrielle
29 route des Industries
37530 Pocé-sur-Cisse
France

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	Diflucan 2 mg/ml Infusionslösung
Belgium, Denmark, Ireland, Italy, Luxembourg, Norway, Poland, United Kingdom (Northern Ireland)	Diflucan
Cyprus, Greece	Fungustatin
France	Triflucan 2 mg/ml, solution pour perfusion
Germany	Diflucan i.v. 2 mg/ml, Infusionslösung
Netherlands	Diflucan I.V. 2 mg/ml
Romania	Diflucan 2 mg/ml soluție perfuzabilă

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The following information is intended for medical or healthcare professionals only:

Intravenous infusion should be administered at a rate not exceeding 10 ml/minute. Diflucan 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 Diflucan 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 5% and 20%
- b) Ringer's solution
- c) Hartmann's solution
- d) Potassium chloride in dextrose
- e) Sodium bicarbonate 4.2% and 5%
- f) Aminosyn 3.5%
- g) Sodium chloride 9 mg/ml (0.9%)
- h) Dialaflex (interperitoneal dialysis Soln 6.36%)

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.

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.

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.