

LEAFLET: INFORMATION FOR THE USER

Diflucan 50 mg, capsule, hard
Diflucan 100 mg, capsule, hard
Diflucan 150 mg, capsule, hard
Diflucan 200 mg, capsule, hard

fluconazole

Read the entire 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.
- Do you have any questions? Contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

Contents of this leaflet

1. What is Diflucan and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the packaging and other information

1. WHAT IS DIFLUCAN AND WHAT IS IT USED FOR?

Diflucan belongs to a group of medicines called 'antifungals'. The active substance is fluconazole.

Diflucan is used to treat fungal infections and can also be used to prevent you from getting a Candida infection. The most common cause of fungal infections is a yeast called Candida.

Adults

- Your doctor may give you this medicine to treat the following types of fungal infections:
 - cryptococcal meningitis – a fungal infection in the brain
 - coccidioidomycosis – a disease of the lungs and respiratory tract
 - infections caused by Candida found in the bloodstream, organs (e.g., heart, lungs), or urinary tract
 - mucosal candidiasis (oral thrush) – infection of the mucous membranes of the mouth, throat, and inflammation of the mucous membranes in denture wearers
 - genital candidiasis – infection of the vagina or penis
 - skin infections – e.g., athlete's foot, ringworm, jock itch, nail infection.

You may also receive Diflucan to:

- prevent cryptococcal meningitis from coming back

- prevent mucosal candidiasis (oral thrush) from coming back
- reduce the recurrence of vaginal yeast infections
- prevent you from getting a Candida infection (if your immune system is weakened and not working properly).

Children and adolescents up to 18 years

Your child's doctor may give him/her this medicine to treat the following types of fungal infections:

- mucosal candidiasis (oral thrush) – infection of the mucous membranes of the mouth, throat
- infections caused by Candida found in the bloodstream, organs (e.g., heart, lungs), or urinary tract
- cryptococcal meningitis – a fungal infection in the brain.

Your child can also receive Diflucan to:

- prevent him/her from getting a Candida infection (if his/her immune system is weakened and not functioning properly)
- prevent cryptococcal meningitis from returning.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR SHOULD YOU BE EXTRA CAUTIOUS WITH IT?

When should you not use this medicine?

- You or your child is allergic to other medicines that you or your child have taken to treat fungal infections, or to any of the substances in this medicine. You can find these substances in section 6. Symptoms may include: itching, skin redness, or difficulty breathing.
- You or your child is taking astemizole, terfenadine (antihistamines for allergies).
- You or your child is taking cisapride (used for stomach problems).
- You or your child is taking pimozone (used in the treatment of mental disorders).
- You or your child is taking quinidine (used for an irregular heartbeat).
- You or your child is taking erythromycin (an antibiotic for the treatment of infections).

When should you be extra cautious with this medicine?

Contact your doctor or pharmacist before using this medicine:

- if you or your child has liver or kidney problems
- if you or your child has heart conditions, including heart rhythm disorders
- if you or your child has abnormal potassium, calcium, or magnesium levels in your or his/her blood
- if you or your child develops severe skin reactions (itching, skin redness, or breathing problems)
- if you or your child develop symptoms of 'adrenal insufficiency', where the adrenal glands do not produce sufficient amounts of certain steroid hormones such as cortisol (chronic or prolonged fatigue, muscle weakness, lack of appetite, weight loss, abdominal pain)
- if you or your child have ever had a severe skin rash or skin peeling, blistering and/or sores in the mouth after taking fluconazole.

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

Contact your doctor or pharmacist if the fungal infection does not improve, as another antifungal treatment may be needed.

Are you taking any other medicines?

Are you or your child taking any other medicines besides Diflucan, or have you or he/she done so recently, or is there a possibility that you or your child will take other medicines in the near future? If so, tell your doctor, the doctor treating your child, or your pharmacist.

Inform your doctor or your child's doctor immediately if you or your child are taking any of the following medicines: astemizole, terfenadine (an antihistamine for treating allergies), cisapride (used for stomach problems), pimozide (used for treating mental disorders), quinidine (used for treating heart rhythm disorders) or erythromycin (an antibiotic for treating infections), as these medicines should not be taken with Diflucan (see section: 'When should you not use this medicine?').

Some medicines may interact with Diflucan. Inform your doctor or your child's doctor if you or your child are taking any of the following medicines. A dose adjustment may be necessary or monitoring to ensure the medicines still have the desired effect:

- rifampicin or rifabutin (antibiotics for infections)
- abrocitinib (used for the treatment of atopic dermatitis, also known as atopic eczema or constitutional eczema)
- alfentanil, fentanyl (used as an anesthetic)
- amitriptyline, nortriptyline (used as an antidepressant)
- amphotericin B, voriconazole (antifungal agent)
- blood thinners 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 seizures)
- nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan (for hypertension: high blood pressure)
- olaparib (used for the treatment of ovarian cancer)
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent rejection in transplants)
- cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar medicines) used in the treatment of cancer
- halofantrine (used in the treatment of malaria)
- statins (atorvastatin, simvastatin, and fluvastatin or similar medicines) used for lowering high cholesterol levels
- methadone (used in pain management)
- celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (non-steroidal anti-inflammatory drugs [NSAIDs])
- agents to prevent pregnancy taken orally (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 in the treatment of asthma)
- tofacitinib (used in the treatment of rheumatoid arthritis)
- tolvaptan used in the treatment of hyponatremia (low sodium levels in your blood) or to slow the decline of kidney function
- vitamin A (dietary supplement)
- ivacaftor (alone or combined with medicines used in the treatment of cystic fibrosis)
- amiodarone (used in a heart rhythm disorder (arrhythmia))
- hydrochlorothiazide (agent to improve urination (diuretic))
- ibrutinib (used in the treatment of blood cancer)
- lurasidone (used in the treatment of schizophrenia)

What should you pay attention to with food?

You can take your medicine with or without food.

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

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

Have you been prescribed a longer treatment course with fluconazole? Then it is necessary to use appropriate contraception during the treatment and for one week after the last dose. Contact your doctor about this.

Are you pregnant, do you think you might be pregnant, or do you want to become pregnant? Then you should not use this medicine, unless your doctor has told you to use it. If you become pregnant while taking this medicine or within 1 week after the last dose, contact your doctor.

If you use fluconazole in the first three or second months of pregnancy, you may have a higher risk of miscarriage. If you take fluconazole in the first three months of pregnancy, you may have a higher risk of your baby being born with heart, bone, and/or muscle abnormalities.

There have been reports of babies born with congenital abnormalities of the skull, ears, and bones of the thigh and elbow. This was in women who received high doses of fluconazole (400 to 800 mg per day) for three months or longer for coccidioidomycosis. The link between fluconazole and these cases is not clear.

You can continue breastfeeding after taking a single dose of 150 mg Diflucan. You should not breastfeed if you are using multiple doses of Diflucan.

Driving ability and the use of machines

When driving vehicles or using machines, you should be aware that dizziness or seizures may occur.

Diflucan contains lactose (milk sugar) and sodium (salt)

This medicine contains a small amount of lactose (milk sugar). If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

Diflucan hard capsules also contain less than 1 mmol sodium (23 mg) per capsule, which means it is essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Swallow the capsule whole with a glass of water. It is best to take your capsules at the same time every day.

The recommended dosages for this medicine for different infections are listed below:

Use in adults

Condition	Dosage
For the treatment of cryptococcal meningitis	400 mg on the first day, then once daily 200 to 400 mg for 6 to 8 weeks, or longer if necessary. The dose may sometimes be increased to 800 mg
To prevent cryptococcal meningitis from returning	once daily 200 mg until you are told to stop
For the treatment of coccidioidomycosis	once daily 200 to 400 mg for 11 months up to a maximum of 24 months or longer if necessary. The dose may sometimes be increased to 800 mg
For the treatment of internal schimmel infections caused by Candida	800 mg on the first day and then once daily 400 mg until you are told to stop
For the treatment of mucosal infections in the moud, throat and inflammations of the mucosa in denture wearers	200 mg to 400 mg on the first day, then once daily 100 mg up to 200 mg until you are told to stop
For the treatment of mucosal candidiasis (oralthrush) – dose depends on site of infection	once daily 50 to 400 mg the duration of 7 to 30 days until you are told to stop
To prevent mucosal infections in the mouth or throat from recurring	once daily 100 to 200 mg, or 3 times per week 200 mg, as long as you are at risk of infection
For the treatment of genital candidiasis	150 mg as a single dose
To prevent the recurrence of vaginal to reduce fungal infections	150 mg every third day with a total of 3 doses (day 1, 4, and 7) and then once a week for 6 months as long as you are at risk of infection
For the treatment of fungal infections	depending on the location of the

of the skin and nails

infection once daily 50 mg, once weekly 150 mg, once weekly 300 to 400 mg for 1 to 4 weeks (up to 6 weeks for athlete's foot; for nail infection, the treatment lasts until the infected nail is replaced)

To prevent you from contracting a Candida infection (if your immune system is weakened and not functioning well) works) 200 to 400 mg once daily as long as you are at risk of infection

Use in adolescents aged 12 to 18 years
Follow the dosage prescribed by your doctor (adult dosage or children's dosage).

Use in children up to the age of 11 years The maximum dose for children is 400 mg per day.

The dose will be determined based on the child's weight in kilograms.

Condition	Daily dose
Mucosal candidiasis (oral thrush) and throat infections caused by Candida – dose and duration depend on the severity and location of infection	once daily 3 mg/kg body weight (on the first day can be 6 mg/kg body weight given)
Cryptococcal meningitis or internal fungal infections caused by Candida	once daily 6 mg to 12 mg/kg body weight
To prevent cryptococcal meningitis from recurring	once daily 6 mg/kg body weight
To prevent children from contracting a Candida infection (if their immune system does not work properly)	once daily 3 mg to 12 mg/kg body weight

Use in children aged 0 to 4 weeks Use in children aged 3 to 4 weeks:
The same dose as above, but administered once every 2 days. The maximum dosage is 12 mg/kg body weight per 48 hours.

Use in children younger than 2 weeks:
The same dose as above, but administered once every 3 days. The maximum dosage is 12 mg/kg body weight per 72 hours.

Use in the elderly
You should receive the usual adult dose unless you have kidney problems.

Use in patients with kidney problems
Your doctor may adjust your dose depending on your kidney function.

Have you used too much of this medicine?
If you take too many capsules at once, you may become ill. Contact your doctor or the emergency department of the nearest hospital immediately. Symptoms of a possible

overdose may include hearing, seeing, feeling, and thinking things that are not there (hallucination and paranoid behavior). Treatment of the symptoms that occur (with supportive measures and if necessary a gastric lavage) may be sufficient.

Have you forgotten to use this medicine?

Do not take a double dose to make up for a forgotten dose. If you have forgotten to take a dose, you should do so as soon as you remember. However, if it is almost time for your next dose, do not take the dose you missed.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Diflucan and seek medical help immediately if you notice any of the following complaints:

- skin rash over a large part of the body, high body temperature, and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

Some people develop allergic reactions, although serious allergic reactions are rare. If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. Tell your doctor immediately if you experience any of the following symptoms:

- sudden wheezing, difficulty breathing, or tightness in the chest
- swollen eyelids, face, or lips
- itching all over the body, redness of the skin, or itchy red spots
- skin rash
- severe skin reactions such as blistering rash (this may occur in the mouth and on the tongue)

Diflucan can affect your liver. Symptoms of liver problems include:

- fatigue
- loss of appetite
- vomiting
- yellowing of your skin or the whites of your eyes (jaundice)

If any of these symptoms occur, stop taking Diflucan and tell your doctor immediately.

Other side effects:

Common side effects (occur in less than 1 in 10 users) are:

- headache
- stomach upset, diarrhea, nausea, vomiting
- increased levels of blood test results in liver function tests

- skin rash

Uncommon side effects (occur in less than 1 in 100 users) are:

- reduced number of red blood cells, which can result in pale skin and weakness or shortness of breath
- reduced appetite
- insomnia, feeling drowsy
- seizure, dizziness, spinning sensation, tingling, prickling or numb feeling, taste changes
- constipation, indigestion, flatulence, dry mouth
- muscle pain
- liver damage and yellowing of the skin or eyes (jaundice)
- striae, blistering (hives/urticaria), itching, increased sweating
- fatigue, general feeling of malaise, fever

Rare side effects (occur in less than 1 in 1000 users) are:

- too low a number of white blood cells that help protect against infections and too low a number of blood cells that help stop bleeding
- red or purple discoloration of the skin, which may be caused by a low number of platelets, other changes in blood cells
- changes in blood chemistry (high cholesterol or fat levels in the blood)
- too little potassium in the blood
- trembling
- abnormal electrocardiogram (ECG), altered heart rate or other heart rhythm
- liver failure
- allergic reactions (sometimes severe), including widespread skin rash with blistering, peeling of the skin, severe skin reactions, swollen lips or face
- hair loss

Side effects of unknown frequency, but which may occur (the frequency cannot be determined from the available data):

- hypersensitivity reaction with skin rash, fever, swollen glands, increase of certain white blood cells (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys, and colon) (drug reaction or rash with eosinophilia and systemic symptoms (DRESS syndrome))

Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to any side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date. You can find it on the packaging after EXP. It includes a month and a year. The last day of that month is the expiry date.
- Store below 30°C.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is fluconazole.
- Each hard capsule contains 50 mg, 100 mg, 150 mg, or 200 mg of fluconazole.
- The other substances in this medicine are:

Contents of the capsules: lactose monohydrate, maize starch, anhydrous colloidal silica, magnesium stearate, and sodium lauryl sulfate (see section 2, Diflucan contains lactose (milk sugar) and sodium (salt)).

Composition of the capsule shell:

Hard capsules 50 mg: gelatin (E441), titanium dioxide (E171), and Patent Blue V (E131)

Hard capsules 100 mg: gelatin (E441), titanium dioxide (E171), erythrosine (E127), and Patent Blue V (E131)

Hard capsules 150 mg: gelatin (E441), titanium dioxide (E171), and Patent Blue V (E131)

Hard capsules 200 mg: gelatin (E441), titanium dioxide (E171), erythrosine (E127), and indigotine (E132)

Printing ink: shellac (glaze), black iron oxide (E172), N-butyl alcohol, dehydrated alcohol, purified water, propylene glycol (E1520), industrial methylated alcohol, isopropyl alcohol, strong ammonia solution, potassium hydroxide (E525).

What does Diflucan look like and what is in a package?

- Diflucan hard capsules of 50 mg have a white lower half with a turquoise blue upper half. They bear the imprint "Pfizer" and the code "FLU-50" in black ink.
- Diflucan hard capsules of 100 mg have a white lower half and a blue upper half. They bear the imprint "Pfizer" and the code "FLU-100" in black ink.
- Diflucan hard capsules of 150 mg have a turquoise blue lower half and a turquoise blue upper half. They bear the imprint "Pfizer" and the code "FLU-150" in black ink.
- Diflucan hard capsules of 200 mg have a white lower half and a purple upper half. They bear the imprint "Pfizer" and the code "FLU-200" in black ink.

Diflucan 50 mg, 100 mg, 150 mg, and 200 mg is available in packages of 1, 2, 3, 4, 6, 7, 10, 12, 14, 20, 28, 30, 42, 50, 60, 100, or 500 hard capsules. Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Pfizer bv

Rivium Westlaan 142

2909 LD Capelle a/d IJssel

Manufacturer

Fareva Amboise

Industrial Zone

29 Route des Industries
37530 Pocé-sur-Cisse
France

Diflucan 50 mg, capsule, hard is registered under RVG 13038.
Diflucan 100 mg, capsule, hard is registered under RVG 14767.
Diflucan 150 mg, capsule, hard is registered under RVG 13039. Diflucan 200 mg, capsule, hard is registered under RVG 14768.

For questions about this medicine, call Pfizer 0800-MEDINFO (63 34 636).

This medicine is registered in member states of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium, Bulgaria, Czech Republic, Denmark, Finland, Ireland, Italy, Luxembourg, Norway, Portugal, United Kingdom (Northern Ireland), Iceland, Sweden	Diflucan
Cyprus, Greece	Fungustatin
Germany	Diflucan 50mg Diflucan 100mg Fungata Diflucan 200mg
Estonia	Diflucan 150mg
France	Triflucan 50 mg capsule Triflucan 100 mg, capsule Triflucan 200 mg, capsule Fluconazole Pfizer 150mg, capsule
Hungary	Diflucan 50 mg hard capsule Diflucan 100 mg hard capsule Diflucan 150 mg hard capsule Diflucan 200 mg hard capsule
Latvia	Diflucan 150 mg hard capsules
Lithuania	Diflucan 50 mg hard capsules Diflucan 150 mg hard capsules
Netherlands	Diflucan 50 mg, capsule, hard Diflucan 100 mg, capsule, hard Diflucan 150 mg, capsule, hard Diflucan 200 mg, capsule, hard
Austria	Diflucan 50 mg capsules Diflucan 100 mg capsules Diflucan 150 mg capsules Diflucan 200 mg capsules
Romania	Diflucan 50 mg capsule Diflucan 150 mg capsule
Slovenia	Diflucan 50 mg hard capsules Diflucan 100 mg hard capsules Diflucan 150 mg hard capsules
Slovakia	Diflucan 50mg Diflucan 100mg

Spain

Diflucan 150mg
Diflucan 50 mg hard capsules
Diflucan 100 mg hard capsules
Diflucan 150 mg hard capsules
Diflucan 200 mg hard capsules

This leaflet was last approved in February 2024.

More information about this medicine is available on the website of the Medicines Evaluation Board (www.cbg-meb.nl).

Transtoyou