

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Diflucan 40 mg/ml, powder for oral suspension

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 further questions? Please 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 them, even if their symptoms 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.

### 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?
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### 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 may 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 condition of the lungs and airways
- 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, skin fungus of legs/groin, nail infection.

You may also receive Diflucan to:

- prevent cryptococcal meningitis from returning
- prevent mucosal candidiasis (oral thrush) from returning

- reduce the recurrence of vaginal yeast infections
- prevent you from getting a Candida infection (if your immune system is weakened and not functioning 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 may 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 BE EXTRA CAUTIOUS?

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 pimozide (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 careful 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 develops symptoms of 'adrenal insufficiency', where the adrenal glands do not produce enough of certain steroid hormones such as cortisol (chronic or long-lasting fatigue, muscle weakness, lack of appetite, weight loss, abdominal pain)
- if you or your child has 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 medical help immediately if you notice any of the complaints 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 alongside 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? Then 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 is taking any of the following medicines: astemizole, terfenadine (an antihistamine for the treatment of allergies), cisapride (used for stomach problems), pimozide (used in the treatment of mental disorders), quinidine (used for the treatment of heart rhythm disorders) or erythromycin (an antibiotic for the treatment of 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 the doctor treating your child 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 in 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 in 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 to lower high cholesterol levels
- methadone (used for pain relief)
- celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (non-steroidal anti-inflammatory drugs [NSAID])
- medicines 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 (reduced 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 for a heart rhythm disorder (arrhythmia))
- hydrochlorothiazide (medicine to help you urinate better (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 before using this medicine.

If you plan 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 or second trimester of pregnancy, you may have an increased risk of miscarriage. If you take fluconazole in the first trimester of pregnancy, you may have an increased risk that your baby will be born with abnormalities of the heart, bones, and/or muscles.

There are 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, powder for oral suspension contains sucrose (sugar), sodium benzoate, and sodium (salt)

- If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.
- Doses of 10 ml contain 5.5 g or more of sugar. Caution is advised in patients with diabetes mellitus.
- May be harmful to the teeth when used for more than 2 weeks.
- The bottle with a capacity of 60 ml contains 83 mg of sodium benzoate per bottle corresponding to 2.38 mg/ml.
- Sodium benzoate can worsen jaundice (yellowing of the skin and eyes) in newborns (younger than 4 weeks).
- After reconstitution, Diflucan 40 mg/ml powder for oral suspension contains less than 1 mmol sodium (23 mg) per 20 ml (maximum recommended dose), meaning it is essentially 'sodium-free'.

### 3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. Unsure about the correct use? Then contact your doctor or pharmacist.

It is best to take your medicine 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 and then once daily 200 to 400 mg for 6 to 8 weeks, or longer if necessary. The dose can sometimes be increased to 800 mg
To prevent cryptococcal meningitis	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 can sometimes be increased to 800 mg
For the treatment of internal fungal 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 mouth, throat, and mucosal inflammations in denture wearers	200 mg to 400 mg on the first day, then once daily 100 mg to 200 mg until you are told to stop
For the treatment of mucosal candidiasis (oral thrush) – dose depends on the location of infection	once daily 50 to 400 mg for 7 to 30 days until you are told that you must stop
To prevent mucosal infections in the	once daily 100 to 200 mg, or 3 times

mouth or throat recurring	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 per week for 6 months as long as you are at risk of infection
For the treatment of fungal infections of the skin and nails	depending on the location of the infection once daily 50 mg, once per week 150 mg, once per week 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 a Candida infection	once daily 200 to 400 mg as long as you
Contract (if your immune system is weakened and does not work properly)	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
Mucousmembrane candidiasis (oral thrush) and throat infections caused by Candida – dose and duration depend on the severity and site of infection	once daily 3 mg/kg body weight (on the first day can be 6 mg/kg body weight given are)
Cryptococcal meningitis or internal fungal infections caused by Candida	once daily 6 mg to 12 mg/kg body weight
To prevent cryptococcal meningitis Returns	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.

#### Instructions for preparing the suspension:

It is recommended that your pharmacist prepares the Diflucan, powder for oral suspension, and gives it to you. However, in cases where the pharmacist does not reconstitute this product, instructions are provided at the end of this leaflet in the section "The following information is intended for healthcare professionals or for patients (if the pharmacist does not reconstitute this product)".

#### Instructions for use:

Shake the closed bottle of the suspension before each use.

#### Instructions for the oral dosing syringe:

Shake the prepared suspension well.

1. Open the bottle (safety cap).
2. Insert the syringe adapter into the neck of the bottle (figure 1).
3. Invert the bottle and syringe and draw up the amount of suspension prescribed by the doctor (figure 2). The amounts on the syringe are indicated in ml. A maximum dose of 400 mg per day should not be exceeded in children (see section "3. How to use this medicine?").
4. Turn the bottle with the syringe upright and detach the syringe from the bottle.
5. The medicine can be administered directly into the mouth using the syringe. Have the patient sit upright during administration. Aim the syringe towards the inside of the cheek and slowly squirt the suspension into the patient's mouth (figure 3).
6. Rinse the dosing syringe after use.
7. Close the bottle with the safety cap; leave the adapter on the neck of the bottle.

For converting the dose of the powder for oral suspension from mg/ml to ml/kg body weight for children, see section 6.

Calculate the dose to be administered in ml for adult patients according to the recommended dosage in mg and the product strength.

#### Have you used too much of this medicine?

If you take too much Diflucan, 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:

- 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 rash with blistering (this can occur in the mouth and on the tongue)

Diflucan can affect your liver. The 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 liver function test results
- skin rash

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

- reduced number of red blood cells, which can cause 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), change the heartbeat 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 with the available data):

- hypersensitivity reaction with skin rash, fever, swollen glands, increase in 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 possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website [www.lareb.nl](http://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. It can be found on the bottle and on the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

Powder for oral suspension:

- Store below 25°C. Keep the bottle tightly closed.
- Store the reconstituted suspension below 30°C. Do not freeze.
- The shelf life of the reconstituted suspension is 28 days.

Do not flush medicines down the sink or toilet and do not throw them in the trash. All remaining suspension should be discarded 28 days after reconstitution. Ask your pharmacist what to do with medicines you no longer use. They will 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. 1 ml of reconstituted suspension contains 40 mg of fluconazole.
- The other substances in this medicine are: sucrose, colloidal anhydrous silica, titanium dioxide (E 171), xanthan gum (E415), sodium citrate, anhydrous citric acid, sodium benzoate (E211), and natural orange flavor (contains orange oil and maltodextrin) (See section 2, Diflucan powder for oral suspension contains sucrose (sugar), sodium benzoate, and sodium (salt)).

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

40 mg/ml, powder for oral suspension in a bottle with a capacity of 60 ml: 35 ml suspension after reconstitution

- Diflucan 40 mg/ml, powder for oral suspension is supplied in a bottle with a capacity of 60 ml containing 24.4 g of powder. After reconstitution, the volume of the suspension is 35 ml.
- Diflucan 40 mg/ml, powder for oral suspension is a dry, white to off-white powder. After adding water to the powder (according to the instructions below in this leaflet), a white to off-white suspension with an orange flavor is formed.
- In each bottle, the mixture of powder and water yields 35 ml of suspension.
- A 5 ml oral dosing syringe with graduations and an adapter fitting the bottle is provided to measure the correct dose.

Marketing authorization holder and manufacturer

Marketing authorization holder

Pfizer bv

Rivium Westlaan 142

2909 LD Capelle a/d IJssel

Manufacturer

Fareva Amboise

Zone Industrielle

29 Route des Industries

37530 Pocé-sur-Cisse

France

This medicine is registered under RVG 15758.

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, Denmark, Finland, Ireland, Italy, Luxembourg, Norway, Portugal, United Kingdom (Northern Ireland), Iceland, Sweden	Diflucan
Germany	Diflucan 40 mg/ml powder for oral suspension
France	Triflucan 10 mg/ml, powder for oral suspension Triflucan 40 mg/ml, powder for oral suspension
Greece	Fungustatin
Hungary	Diflucan 40 mg/ml powder for oral suspension
Netherlands	Diflucan 10 mg/ml, powder for oral suspension Diflucan 40 mg/ml, powder for oral suspension
Austria	Diflucan 40 mg/ml dry syrup
Slovenia	Diflucan 10 mg/ml powder for oral suspension Diflucan 40 mg/ml powder for oral suspension
Slovakia	Diflucan P.O.S. 40 mg/ml
Spain	Diflucan 10 mg/ml powder for oral suspension Diflucan 40 mg/ml powder for oral suspension

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](http://www.cbg-meb.nl)).

The following information is intended for healthcare professionals or for patients (if the pharmacist does not reconstitute this product): Instructions for preparing the suspension:

The reconstituted suspension forms a white to off-white suspension with an orange flavor after reconstitution.

40 mg/ml, powder for oral suspension in a bottle with a capacity of 60 ml: 35 ml suspension

after reconstitution Tap the bottle to loosen the powder.

1. Reconstitute by adding 24 ml of water. First add a small amount of non-carbonated water and shake vigorously. Then add water up to the level marked (
2. Reconstitute by adding 24 ml of water. First, add a small amount of non-carbonated water and shake vigorously. Then add water up to the marked level ( ) on the bottle (this corresponds to the required 24 ml of water in total).) on the bottle (in total this corresponds to the required 24 ml water).
3. Shake well for 1 to 2 minutes until a well-mixed suspension is obtained.
4. After reconstitution, the usable amount is 35 ml.
5. Write the expiration date of the reconstituted suspension on the bottle label (the shelf life of the reconstituted suspension is 28 days). Any unused suspension should not be used after this date and should be returned to the pharmacist.

Converting the dose of the powder for oral suspension from mg/ml to ml/kg body weight for children:

Diflucan 40 mg/ml powder for oral suspension:

In children, Diflucan powder for oral suspension should be measured as accurately as possible according to the following formula:

$$\text{Dose in ml/day} = \frac{\text{weight of the child (kg)} * \text{prescribed dosage (mg/kg)}}{\text{product strength (mg/ml)}}$$

The distance between two consecutive graduation marks represents 0.2 ml. For intermediate weights and dosages, the dose to be administered should be calculated and then rounded up or down to the nearest graduation mark on the oral dosing syringe:

For example: a child weighing 23 kg for whom a Diflucan dosage of 6 mg/kg/day is prescribed should receive 138 mg/day, equivalent to 3.45 ml of the 40 mg/ml oral suspension. The dose can be rounded to 3.4 ml, the nearest graduation mark on the oral dosing syringe, to administer the full dose.

A maximum dose of 400 mg per day should not be exceeded in children (see table \*). The use of Diflucan 40 mg/ml powder for oral suspension is not recommended for a body weight under 15 kg. For a body weight under 15 kg, it is recommended to use Diflucan 10 mg/ml powder for oral suspension.

Table with dosage examples:

Dosage (corresponding dose in ml/day)		3	6	12
Weight kg	mg/kg/day	mg/kg/day	mg/kg/day	mg/kg/day

15 kg	1.2 ml	2.2 ml	4.6 ml
20 kg	1.6 ml	3.0 ml	6.0 ml
25 kg	1.8 ml	3.8 ml	7.6 ml
30 kg	2.2 ml	4.6 ml	9.0 ml
35 kg	2.6 ml	5.2 ml	10.0 ml*
40 kg	3.0 ml	6.0 ml	10.0 ml*
50 kg	3.8 ml	7.6 ml	10.0 ml*

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