

Package leaflet: Information for the user

Diflucan® 40 mg/ml powder for oral suspension

(fluconazole)

This product is available as the above name but will be referred to as Diflucan throughout this leaflet. Please note that this leaflet also contains information on other strength (Diflucan® 10 mg/ml powder for oral suspension).

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. 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 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
- Genital thrush - infection of the vagina or penis
- Skin infections - e.g. athlete’s foot, ringworm, jock itch, nail infection

You might also be given Diflucan to:

- stop cryptococcal meningitis from coming back
- stop mucosal thrush from coming back
- reduce recurrence of vaginal thrush
- 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 (hypersensitive) 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 pimozone (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 pharmacist 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 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 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)

Diflucan with food and drink

Diflucan can be taken with or without food.

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 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 sucrose (sugar), sodium benzoate (E211) and sodium (salt)

- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- doses of 10 ml contain 5.5 g or more of sugar. This should be taken into account in patients with diabetes mellitus.
- may be harmful to teeth if used for periods of longer than 2 weeks.
- the 60 ml capacity bottle contains 83 mg of sodium benzoate per bottle which is equivalent to 2.38 mg/ml.
- sodium benzoate (E211) may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- when reconstituted, Diflucan 10 mg/ml powder for oral suspension contains 1.13 mg sodium per ml. This is equivalent to 4.5% of the recommended maximum daily dietary intake of sodium for an adult.
- when reconstituted, Diflucan 40 mg/ml powder for oral suspension contains less than 1 mmol sodium (23 mg) per 20 ml (maximum recommended dose), that is to say essentially ‘sodium-free’.

3. How to take Diflucan

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

It is best to take medicine at the same time each day.

The recommended doses of this medicine for different infections are below:

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 the 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 of mouth and 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 treat genital thrush	150 mg as a single dose
To reduce recurrence of vaginal thrush	150 mg every third day for a total of 3 doses (day 1, 4 and 7) and then once a week for 6 months while you are at risk of getting an infection
To treat fungal skin and nail infections	Depending on the site of the infection 50 mg once daily, 150 mg once weekly, 300 to 400 mg once weekly for 1 to 4 weeks (Athlete’s foot may be up to 6 weeks, for nail infection treatment until infected nail is replaced)
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.

Instructions to make up the suspension:

It is recommended that your pharmacist makes up Diflucan powder for oral suspension before giving it to you. However, 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 (where the pharmacist does not reconstitute this product)".

Instructions for use:

Shake the closed bottle of the suspension every time before using.

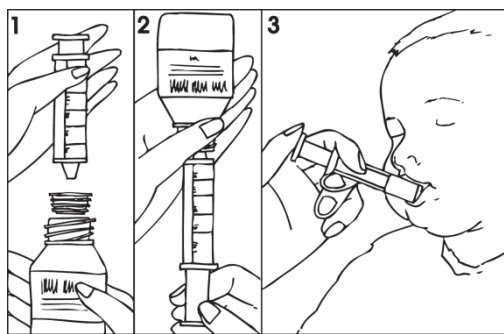
Instructions to use the oral syringe:

Shake the prepared suspension well.

1. Open the bottle (safety cap);
2. Insert the adapter fitted onto the oral syringe into the bottle neck (Figure 1);
3. Turn the bottle with the oral syringe upside down and withdraw the quantity of suspension prescribed by the doctor (Figure 2). The marks on the oral syringe are shown in ml.

A maximum dose of 400 mg daily should not be exceeded in children. (see section "3. How to take Diflucan").

4. Turn the bottle with the oral syringe the right way up and remove the oral syringe from the bottle;
5. The medicinal product may be given directly into the mouth from the oral syringe. The patient should remain upright during administration. Point the oral syringe at the inside of the cheek; release the suspension slowly into the patient's mouth (Figure 3).
6. Rinse the oral syringe.
7. Close the bottle with the safety cap; the adapter will remain on the bottle neck.



For dose conversion of the powder for oral suspension from mg/ml to ml/kg body weight (BW) for paediatric patients, see section 6.

For adult patients, please calculate the dose in ml to administer according to the posology in mg recommended and the product strength.

If you take more Diflucan than you should

Taking too much Diflucan may make you unwell. Contact your doctor or your nearest hospital casualty department at once. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behaviour). Symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.

If you forget to take Diflucan

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

If you have any further questions on the use of this medicine, ask 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 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 the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 bottle and the outer carton after EXP. The expiry date refers to the last day of that month.
- **Powder for oral suspension:** Do not store above 25°C. Keep the bottle tightly closed.
- **Reconstituted suspension:** Do not store above 30°C. Do not freeze.
- The shelf life of the reconstituted suspension is 28 days.
- Do not throw away any medicines via wastewater or household waste. Any remaining suspension should be discarded 28 days after reconstitution. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- If your medicine becomes discoloured or show signs of any deterioration, consult your doctor or pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Diflucan contains

- The active substance is fluconazole. Each ml of reconstituted suspension contains 40 mg fluconazole.
- The other ingredients are: sucrose, colloidal anhydrous silica, titanium dioxide (E 171), xanthan gum (E415), sodium citrate, citric acid anhydrous, sodium benzoate (E211) and natural orange flavour (containing orange oil and maltodextrin) (see section 2, Diflucan contains sucrose (sugar), sodium benzoate (E211) and sodium (salt)).

What Diflucan looks like and contents of the pack:

- Diflucan comes as a 60 ml capacity bottle which contains 24.4 g powder. After reconstitution, the volume of the suspension is 35 ml.
- Diflucan is a dry white to off-white powder. After adding water to the powder (as instructed in this leaflet below) a white to off-white orange flavoured suspension is produced.
- In each bottle the mixture of powder and water makes 35 ml of suspension.
- Diflucan comes in a plastic bottle with a child resistant cap and a tamper evident seal. A 5 ml graduated plastic oral syringe with a plastic press-in bottle adaptor is provided to measure the correct dose.

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POM

Manufactured by Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France. Procured from within the EU and repackaged by the Product Licence holder: O.P.D. Laboratories Ltd., Unit 6 Colonial Way, Watford, Herts WD24 4PR.

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To request a copy of this leaflet in Braille, large print or audio please call 01923 332 796.

Diflucan is a registered trademark of Pfizer group of companies.

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

Instructions to make up the suspension:

The reconstituted suspension will provide a white to off-white orange-flavoured suspension after reconstitution.

10 mg/ml or 40 mg/ml powder for oral suspension in 60 ml capacity bottle: 35 ml suspension after reconstitution

1. Tap the bottle to release the powder.
2. Reconstitute by adding 24 ml of water. First, add a small quantity of still water and shake it vigorously. Then, add water up to the level marked (▶) on the bottle (this corresponds in total to adding the required 24 ml of water).
3. Shake well for 1 to 2 minutes to obtain a well mixed suspension.
4. After reconstitution there will be a usable volume of 35 ml.
5. Write the expiry 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 your pharmacist.

Dose conversion of the powder for oral suspension from mg/ml to ml/kg body weight (BW) for paediatric patients:

Diflucan 10 mg/ml powder for oral suspension:

In children Diflucan powder for oral suspension should be measured as closely as possible according to the following equation:

Dose in ml/day =

$$\frac{\text{child's weight (kg)} \times \text{prescribed dosage (mg/kg)}}{\text{product strength (mg/ml)}}$$

The graduations of the oral syringe are in increments of 0.2 ml. Therefore, for intermediate weights and dosages, the dose to be given in ml should be calculated then rounded up or down to the nearest graduation of the oral syringe:

For example, a child weighing 11 kg prescribed Diflucan 3 mg/kg/day should receive 33 mg/day, equivalent to 3.3 ml of the 10 mg/ml oral suspension. The dose may be rounded up to 3.4 ml, the nearest graduation on the oral syringe to provide the full dose.

A maximum dose of 400 mg daily should not be exceeded in the paediatric population (see table *).

The use of Diflucan 10 mg/ml powder for oral suspension is not recommended for doses > 15.0 ml (see table for doses highlighted in grey). When doses exceed 15.0 ml, it is recommended to use Diflucan 40 mg/ml powder for oral suspension.

Table Dosage examples:

Weight Kg	Posology (Corresponding dose in ml/day)		
	3 mg/kg /day	6 mg/kg /day	12 mg/kg /day
3 kg	1.0 ml	1.8 ml	3.6 ml
5 kg	1.6 ml	3.0 ml	6.0 ml
7.5 kg	2.2 ml	4.6 ml	9.0 ml
10 kg	3.0 ml	6.0 ml	12.0 ml
12.5 kg	3.8 ml	7.6 ml	15.0 ml
15 kg	4.6 ml	9.0 ml	18.0 ml
20 kg	6.0 ml	12.0 ml	24.0 ml
25 kg	7.6 ml	15.0 ml	30.0 ml
30 kg	9.0 ml	18.0 ml	36.0 ml
35 kg	10.6 ml	21.0 ml	40.0 ml*
40 kg	12.0 ml	24.0 ml	40.0 ml*
45 kg	13.6 ml	27.0 ml	40.0 ml*

Diflucan 40 mg/ml powder for oral suspension:

In children Diflucan powder for oral suspension should be measured as closely as possible according to the following equation:

Dose in ml/day =

$$\frac{\text{child's weight (kg)} \times \text{prescribed dosage (mg/kg)}}{\text{product strength (mg/ml)}}$$

The graduations of the oral syringe are in increments of 0.2 ml. Therefore, for intermediate weights and dosages, the dose to be given in ml should be calculated then rounded up or down to the nearest graduation of the oral syringe:

For example, a child weighing 23 kg prescribed Diflucan 6 mg/kg/day should receive 138 mg/day, equivalent to 3.45 ml of the 40 mg/ml oral suspension. The dose may be rounded down to 3.4 ml, the nearest graduation on the oral syringe to provide the full dose.

A maximum dose of 400 mg daily should not be exceeded in the paediatric population (see table *).

The use of Diflucan 40 mg/ml powder for oral suspension is not recommended for weights under 15 kg. For weights under 15 kg, it is recommended to use Diflucan 10 mg/ml powder for oral suspension.

Weight Kg	Posology (Corresponding dose in ml/day)		
	3 mg/kg /day	6 mg/kg /day	12 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*

Package leaflet: Information for the user

Fluconazole 40 mg/ml powder for oral suspension

This product is available as the above name but will be referred to as Fluconazole throughout this leaflet. Please note that this leaflet also contains information on other strength (Fluconazole 10 mg/ml powder for oral suspension).

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. See section 4.

What is in this leaflet:

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

1. What Fluconazole is and what it is used for

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

Fluconazole 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
- Genital thrush - infection of the vagina or penis
- Skin infections - e.g. athlete’s foot, ringworm, jock itch, nail infection

You might also be given Fluconazole to:

- stop cryptococcal meningitis from coming back
- stop mucosal thrush from coming back
- reduce recurrence of vaginal thrush
- 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 Fluconazole 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 Fluconazole

Do not take Fluconazole

- if you are allergic (hypersensitive) 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 pimoizide (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 pharmacist before taking Fluconazole

- 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 Fluconazole 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 Fluconazole

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 pimoizide (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 Fluconazole (see section: “Do not take Fluconazole if you”).

There are some medicines that may interact with Fluconazole. 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)

Fluconazole with food and drink

Fluconazole can be taken with or without food.

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 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 Fluconazole 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 occidoidomycosis. The link between fluconazole and these cases is not clear. You can continue breast-feeding after taking a single dose of 150 mg Fluconazole. You should not breast-feed if you are taking a repeated dose of Fluconazole.

Driving and using machines

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

Fluconazole contains sucrose (sugar), sodium benzoate (E211) and sodium (salt)

- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- doses of 10 ml contain 5.5 g or more of sugar. This should be taken into account in patients with diabetes mellitus.
- may be harmful to teeth if used for periods of longer than 2 weeks.
- the 60 ml capacity bottle contains 83 mg of sodium benzoate per bottle which is equivalent to 2.38 mg/ml.
- sodium benzoate (E211) may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- when reconstituted, Fluconazole 10 mg/ml powder for oral suspension contains 1.13 mg sodium per ml. This is equivalent to 4.5% of the recommended maximum daily dietary intake of sodium for an adult.
- when reconstituted, Fluconazole 40 mg/ml powder for oral suspension contains less than 1 mmol sodium (23 mg) per 20 ml (maximum recommended dose), that is to say essentially ‘sodium-free’.

3. How to take Fluconazole

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

It is best to take medicine at the same time each day.

The recommended doses of this medicine for different infections are below:

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 the 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 of mouth and 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 treat genital thrush	150 mg as a single dose
To reduce recurrence of vaginal thrush	150 mg every third day for a total of 3 doses (day 1, 4 and 7) and then once a week for 6 months while you are at risk of getting an infection
To treat fungal skin and nail infections	Depending on the site of the infection 50 mg once daily, 150 mg once weekly, 300 to 400 mg once weekly for 1 to 4 weeks (Athlete’s foot may be up to 6 weeks, for nail infection treatment until infected nail is replaced)
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.

Instructions to make up the suspension:

It is recommended that your pharmacist makes up Fluconazole powder for oral suspension before giving it to you. However, 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 (where the pharmacist does not reconstitute this product)".

Instructions for use:

Shake the closed bottle of the suspension every time before using.

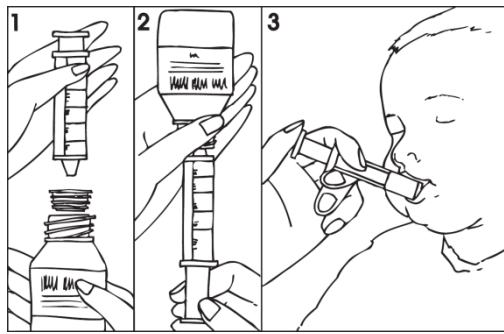
Instructions to use the oral syringe:

Shake the prepared suspension well.

1. Open the bottle (safety cap);
2. Insert the adapter fitted onto the oral syringe into the bottle neck (Figure 1);
3. Turn the bottle with the oral syringe upside down and withdraw the quantity of suspension prescribed by the doctor (Figure 2). The marks on the oral syringe are shown in ml.

A maximum dose of 400 mg daily should not be exceeded in children. (see section "3. How to take Fluconazole").

4. Turn the bottle with the oral syringe the right way up and remove the oral syringe from the bottle;
5. The medicinal product may be given directly into the mouth from the oral syringe. The patient should remain upright during administration. Point the oral syringe at the inside of the cheek; release the suspension slowly into the patient's mouth (Figure 3).
6. Rinse the oral syringe.
7. Close the bottle with the safety cap; the adapter will remain on the bottle neck.



For dose conversion of the powder for oral suspension from mg/ml to ml/kg body weight (BW) for paediatric patients, see section 6.

For adult patients, please calculate the dose in ml to administer according to the posology in mg recommended and the product strength.

If you take more Fluconazole than you should

Taking too much Fluconazole may make you unwell. Contact your doctor or your nearest hospital casualty department at once. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behaviour). Symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.

If you forget to take Fluconazole

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Fluconazole 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).

Fluconazole 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 Fluconazole 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 the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Fluconazole

- **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 bottle and the outer carton after EXP. The expiry date refers to the last day of that month.
- **Powder for oral suspension:** Do not store above 25°C. Keep the bottle tightly closed.
- **Reconstituted suspension:** Do not store above 30°C. Do not freeze.
- The shelf life of the reconstituted suspension is 28 days.
- Do not throw away any medicines via wastewater or household waste. Any remaining suspension should be discarded 28 days after reconstitution. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- If your medicine becomes discoloured or show signs of any deterioration, consult your doctor or pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Fluconazole contains

- The active substance is fluconazole. Each ml of reconstituted suspension contains 40 mg fluconazole.
- The other ingredients are: sucrose, colloidal anhydrous silica, titanium dioxide (E 171), xanthan gum (E415), sodium citrate, citric acid anhydrous, sodium benzoate (E211) and natural orange flavour (containing orange oil and maltodextrin) (see section 2, Fluconazole contains sucrose (sugar), sodium benzoate (E211) and sodium (salt)).

What Fluconazole looks like and contents of the pack:

- Fluconazole comes as a 60 ml capacity bottle which contains 24.4 g powder. After reconstitution, the volume of the suspension is 35 ml.
- Fluconazole is a dry white to off-white powder. After adding water to the powder (as instructed in this leaflet below) a white to off-white orange flavoured suspension is produced.
- In each bottle the mixture of powder and water makes 35 ml of suspension.
- Fluconazole comes in a plastic bottle with a child resistant cap and a tamper evident seal. A 5 ml graduated plastic oral syringe with a plastic press-in bottle adaptor is provided to measure the correct dose.

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POM

Manufactured by Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France. Procured from within the EU and repackaged by the Product Licence holder: O.P.D. Laboratories Ltd., Unit 6 Colonial Way, Watford, Herts WD24 4PR.

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To request a copy of this leaflet in Braille, large print or audio please call 01923 332 796.

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

Instructions to make up the suspension:

The reconstituted suspension will provide a white to off-white orange-flavoured suspension after reconstitution.

10 mg/ml or 40 mg/ml powder for oral suspension in 60 ml capacity bottle: 35 ml suspension after reconstitution

1. Tap the bottle to release the powder.
2. Reconstitute by adding 24 ml of water. First, add a small quantity of still water and shake it vigorously. Then, add water up to the level marked (➡) on the bottle (this corresponds in total to adding the required 24 ml of water).
3. Shake well for 1 to 2 minutes to obtain a well mixed suspension.
4. After reconstitution there will be a usable volume of 35 ml.
5. Write the expiry 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 your pharmacist.

Dose conversion of the powder for oral suspension from mg/ml to ml/kg body weight (BW) for paediatric patients:

Fluconazole 10 mg/ml powder for oral suspension:

In children Fluconazole powder for oral suspension should be measured as closely as possible according to the following equation:

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

The graduations of the oral syringe are in increments of 0.2 ml. Therefore, for intermediate weights and dosages, the dose to be given in ml should be calculated then rounded up or down to the nearest graduation of the oral syringe:

For example, a child weighing 11 kg prescribed Fluconazole 3 mg/kg/day should receive 33 mg/day, equivalent to 3.3 ml of the 10 mg/ml oral suspension. The dose may be rounded up to 3.4 ml, the nearest graduation on the oral syringe to provide the full dose.

A maximum dose of 400 mg daily should not be exceeded in the paediatric population (see table *).

The use of Fluconazole 10 mg/ml powder for oral suspension is not recommended for doses > 15.0 ml (see table for doses highlighted in grey). When doses exceed 15.0 ml, it is recommended to use Fluconazole 40 mg/ml powder for oral suspension.

Table Dosage examples:

Weight Kg	Posology (Corresponding dose in ml/day)		
	3 mg/kg /day	6 mg/kg /day	12 mg/kg /day
3 kg	1.0 ml	1.8 ml	3.6 ml
5 kg	1.6 ml	3.0 ml	6.0 ml
7.5 kg	2.2 ml	4.6 ml	9.0 ml
10 kg	3.0 ml	6.0 ml	12.0 ml
12.5 kg	3.8 ml	7.6 ml	15.0 ml
15 kg	4.6 ml	9.0 ml	18.0 ml
20 kg	6.0 ml	12.0 ml	24.0 ml
25 kg	7.6 ml	15.0 ml	30.0 ml
30 kg	9.0 ml	18.0 ml	36.0 ml
35 kg	10.6 ml	21.0 ml	40.0 ml*
40 kg	12.0 ml	24.0 ml	40.0 ml*
45 kg	13.6 ml	27.0 ml	40.0 ml*

Fluconazole 40 mg/ml powder for oral suspension:

In children Fluconazole powder for oral suspension should be measured as closely as possible according to the following equation:

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

The graduations of the oral syringe are in increments of 0.2 ml. Therefore, for intermediate weights and dosages, the dose to be given in ml should be calculated then rounded up or down to the nearest graduation of the oral syringe:

For example, a child weighing 23 kg prescribed Fluconazole 6 mg/kg/day should receive 138 mg/day, equivalent to 3.45 ml of the 40 mg/ml oral suspension. The dose may be rounded down to 3.4 ml, the nearest graduation on the oral syringe to provide the full dose.

A maximum dose of 400 mg daily should not be exceeded in the paediatric population (see table *).

The use of Fluconazole 40 mg/ml powder for oral suspension is not recommended for weights under 15 kg. For weights under 15 kg, it is recommended to use Fluconazole 10 mg/ml powder for oral suspension.

Weight Kg	Posology (Corresponding dose in ml/day)		
	3 mg/kg /day	6 mg/kg /day	12 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*