

DIFLUCAN[®] CAPSULES

Fluconazole (50 mg, 100 mg, 150 mg)

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What DIFLUCAN is used for

DIFLUCAN is used to treat infections caused by fungi and may also be used to prevent you from getting fungal infections.

You might be given this medicine by your doctor to treat the following types of fungal infections:

- cryptococcal meningitis (fungal infection in the brain);
- infections caused by *Candida* in the bloodstream, body organs (e.g., heart, lungs) or urinary tract;
- mucosal thrush (infection affecting the lining of the mouth, throat and dentures);
- genital thrush (infection of the vagina or penis);
- skin infections (e.g., Athlete's foot, ringworm, jock itch).

You might also be given DIFLUCAN to prevent recurrence of:

- fungal infection in the brain
- mucosal thrush;
- vaginal thrush;
- infection caused by *Candida* (if your immune system is weak and not working properly).

How DIFLUCAN works

DIFLUCAN belongs to a group of medicines called "antifungals". The active substance is fluconazole. It works by inhibiting the growth of fungi that cause infection.

Before you use DIFLUCAN

- When you must not use it

Do not take DIFLUCAN if you:

- are allergic (hypersensitive) to fluconazole or to other medicines you have taken to treat fungal infections or to any of the other ingredients of DIFLUCAN;
- are taking astemizole, terfenadine (antihistamine medicines for allergies);
- are taking cisapride (used for stomach upsets);
- are taking pimozide (used for treating mental illness);
- are taking quinidine (used for treating heart arrhythmia);
- are taking erythromycin (an antibiotic for treating infections).

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take DIFLUCAN while you are pregnant unless your doctor has told you to.

There is a risk of abortion and congenital abnormalities in infants whose mothers are treated with single or repeated dose of 150 mg DIFLUCAN in first trimester. You should not take DIFLUCAN capsules while you are pregnant unless prescribed by your doctor due to severe or potentially life threatening fungal infections. Your doctor will tell you the risk to your fetus if you are taking it during pregnancy or if you become pregnant while taking it.

DIFLUCAN passes into breast milk hence its repeated use or high-dose in breast-feeding mothers is not recommended. You can continue breast-feeding after taking a single dose of 150 mg DIFLUCAN.

- Before you start to use it

Talk to your doctor before taking DIFLUCAN if you:

- are pregnant;
- effective contraceptive measures should be considered in women of child-bearing potential and should continue throughout the treatment period and for approximately 1 week (5 to 6 half-lives) after the final dose;
- have liver or kidney problems;
- have drug reaction with eosinophilia and systemic symptoms (DRESS);
- suffer from heart disease, including heart rhythm problems;
- suffer from AIDS;
- suffer from electrolyte abnormalities;
- have candidiasis;
- have galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption;
- develop severe skin reactions (itching, blistering eruption on the surface of the skin, reddening of the skin or difficulty in breathing);
- you have low levels of potassium in blood and advanced cardiac failure.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are taking any of the below medicines as these should not be taken with DIFLUCAN:

- astemizole, terfenadine (an antihistamine for treating allergies);
- cisapride (used for stomach upsets);
- pimozide (used for treating mental illness);
- quinidine (used for treating heart

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- arrhythmia);
- erythromycin (an antibiotic for treating infections);
- amiodarone (used to treat irregular heartbeat);
- lemborexant (used to treat insomnia).

There are some medicines that may interact with DIFLUCAN. Make sure your doctor knows if you are taking any of the following medicines:

- hydrochlorothiazide (water pills, used to treat high blood pressure and fluid retention);
- 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-depressants);
- amphotericin B, voriconazole (anti-fungals);
- warfarin or similar medicines (blood thinners to prevent blood clots);
- benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety;
- carbamazepine, phenytoin (used for treating fits);
- nifedipine, isradipine, amlodipine, felodipine, verapamil and losartan (for high blood pressure);
- olaparib (used for treating ovarian cancer);
- cyclosporin, 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, saquinavir (used in HIV-infected patients);
- chlorpropamide, glibenclamide, glipizide or tolbutamide (medicines for diabetes);
- theophylline (used to control asthma);
- vitamin A (nutritional supplement);
- tofacitinib (used to treat rheumatoid arthritis);
- ibrutinib (used to treat certain cancers);
- ivacaftor (used to treat cystic fibrosis);
- lurasidone (used to treat schizophrenia and bipolar disorder);
- tolvaptan (used to treat low levels of salt (sodium) in blood).

This is not a complete list of medications to be careful with, please ask your doctor or pharmacist for further information.

How to use DIFLUCAN

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The daily dose of DIFLUCAN is based on the nature and severity of the fungal infection.

Use in Adults

- Vaginal candidiasis (vaginal thrush):
To treat vaginal candidiasis or *Candida balanitis*, a 150 mg single oral dose may be used.
To reduce recurrence of vaginal thrush, a 150 mg once monthly dose may be used and the duration of therapy ranges from 4-12

months.

- Cryptococcal meningitis (fungal infection in the brain):
To treat cryptococcal meningitis, the usual dose is 400 mg on the first day followed by 200 mg to 400 mg once daily for 6 to 8 weeks or longer if needed.

For the prevention of relapse of cryptococcal meningitis in patients with AIDS, after the patient receives a full course of primary therapy, DIFLUCAN may be used indefinitely at a daily dose of 200 mg.

- Infections caused by *Candida* in the bloodstream and body organs:
The usual dose is 400 mg on the first day followed by 200 mg once daily (may be increased to 400 mg once daily).

- Mucosal thrush except genital thrush:
The usual dose is 50 mg to 100 mg once daily for 7 to 30 days until you are told to stop (dose depends on where the infection is located).

- For the prevention of relapse of oral thrush in patients with AIDS, after the patient receives a full course of primary therapy, DIFLUCAN may be used at a 150 mg once weekly dose.
- To prevent infection caused by *Candida*:
The recommended dose is 50 to 400 mg once daily, based on the patient's risk for developing fungal infection. For patients at high risk of infection affecting the entire body, the recommended daily dose is 400 mg once daily.
- For fungal skin infections (e.g., athlete's foot, ringworm, jock itch and *Candida* infections), the recommended dose is 150 mg once weekly or 50 mg once daily. Duration of treatment is normally 2 to 4 weeks but athlete's foot may

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require treatment for up to 6 weeks.

- For tinea versicolor (characterised by discoloured patches commonly seen on the neck, chest, back, arms or abdomen), the recommended dose is 300 mg once weekly for 2 weeks; a third weekly dose of 300 mg may be needed in some patients, whereas, in some patients, a single dose of 300 to 400 mg may be sufficient. Alternatively, 50 mg once daily may be used for 2 to 4 weeks.

Use in Children

DIFLUCAN is used in children as a single dose each day. The dose will be based on the child's weight in kilograms.

Your doctor will determine the right dose according to your child's weight and condition.

Elderly

The usual adult dose should be used unless you have kidney problems.

Individuals with kidney problems

Your doctor may change your dose, depending on your kidney function.

- When to use it

Use as directed by your doctor or pharmacist. DIFLUCAN capsule should be swallowed whole.

- How long to use it

Continue taking DIFLUCAN for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double

dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many capsules may cause hallucinations (such as hearing, seeing, feeling and thinking things that are not real) and paranoid behavior (unfounded distrust and suspiciousness of others).

While you are using it

- Things you must do

Tell your doctor if you develop signs of 'adrenal insufficiency' where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking DIFLUCAN.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give DIFLUCAN to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

DIFLUCAN capsule contains lactose (a type of sugar). If you have been

told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Driving and using machines

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

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

In some patients, particularly those with serious diseases such as AIDS and cancer, DIFLUCAN can cause changes in kidney and haematological (blood) function test results and liver problems.

Common side effects (affects $\geq 1/100$ to $< 1/10$ people)

- headache
- stomach pain
- diarrhea
- nausea
- vomiting
- increase in levels of certain liver enzymes
- rash.

Serious side effects

- sudden wheezing, difficulty in breathing or tightness in the chest
- swelling of eyelids, face or lips
- abnormal electrocardiogram (ECG), change in heart rate or rhythm
- itching all over the body, reddening of the skin or itchy red spots
- severe skin reactions such as a rash that causes blistering
- liver damage and yellowing of the skin and eyes (jaundice)

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not

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listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of DIFLUCAN

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Fluconazole capsule 50 mg is a turquoise and white, opaque No. 4 capsule over-printed with the Pfizer logo and 'FLU 50' and containing white powder.

Fluconazole capsule 100 mg is a white and blue opaque, No. 2 capsule over-printed with the Pfizer logo and the code 'FLU-100' and containing a white powder.

Fluconazole capsule 150 mg is a turquoise, opaque No. 1 capsule over-printed with the Pfizer logo and 'FLU 150' and containing white powder.

- Ingredients

- Active ingredient

Fluconazole

- Inactive ingredients

Lactose,

Maize starch,
Colloidal silicon dioxide,
Magnesium stearate,
Sodium lauryl sulphate.

- MAL number

Diflucan capsule 50 mg:
MAL19913229ACZ
Diflucan capsule 100 mg:
MAL19920034ACZ
Diflucan capsule 150 mg:
MAL19913230ACZ

Manufacturer

Manufactured by:
Fareva Amboise,
Pocé-sur-Cisse, France

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11
Wisma Averis, Tower 2
Avenue 5, Bangsar South
No. 8, Jalan Kerinchi
59200 Kuala Lumpur, Malaysia

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