

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diflucan 150mg Capsules

Fluconazole

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Diflucan Capsules are and what they are used for
2. Before you take Diflucan
3. How to take Diflucan
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(Pack shot)

1. What Diflucan capsules are and what they are used for

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

Diflucan is used to treat infections caused by fungi including yeasts. The most common cause of fungal infections is a yeast called Candida.

You may be given this medicine by your doctor to treat genital thrush, an infection of the vagina or penis.

2. Before you take Diflucan

Do not take Diflucan if you

- have ever had an allergic reaction to:
 - any of the ingredients of Diflucan
 - other medicines you have taken to treat a fungal infection.
The symptoms may include itching, reddening of the skin or difficulty in breathing.
- are taking terfenadine or astemizole (an antihistamine for allergies)
- are taking cisapride (used for stomach upsets)
- are taking pimozide (for treating schizophrenia)
- are taking quinidine (used for irregular heart beats)

Take special care with Diflucan

Tell your doctor if you:

- are aged under 16 years
- have liver or kidney problems
- suffer from heart disease, including heart rhythm problems
- have abnormal levels of potassium, calcium or magnesium in your blood

Taking other medicines

Tell your doctor, immediately if you are taking Terfenadine or astemizole (an antihistamine for treating allergies) or Cisapride (used for stomach upsets) as these should not be taken with Diflucan.

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

- warfarin (or similar drugs) that thin the blood to prevent blood clots
- calcium channel blockers or losartan for lowering blood pressure
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- vitamin A (as a trans-retinoid acid used to treat acne)
 - water tablets, such as hydrochlorothiazide, used to treat fluid retention and high blood pressure
 - fluvastatin (for lowering cholesterol)
 - midazolam used to help you sleep or for anxiety
 - carbamazepine or phenytoin (used to control epilepsy)
 - medicines for treating infections (antibiotics) such as azithromycin, erythromycin rifampicin or rifabutin
 - amphotericin B (used to treat fungal infections)
 - halofantrine (to treat malaria)
 - Cyclosporin, sirolimus or tacrolimus (to prevent transplant rejection)
 - theophylline (used to control asthma)
 - alfentanil, fentanyl or methadone (for treating pain)
 - non-steroidal anti-inflammatory drugs (such as aspirin and ibuprofen) that are used to treat pain and fever
 - celecoxib (used to treat some types of arthritis)
 - amitriptyline, nortriptyline (used to treat migraine)
 - cyclophosphamide, prednisone or vinca alkaloids (for treating some forms of leukaemia)
 - saquinavir or zidovudine, also known as AZT (used in HIV-infected patients)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

You should not take Diflucan while you are pregnant or if you are breast feeding.

Driving and using machines

Treatment with Diflucan has occasionally lead to dizziness or seizures to occur and could affect your ability to drive or use machinery.

Important information about some of the ingredients

This medicine contains a small amount of lactose (sugar), if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicine.

3. How to take Diflucan

Always take Diflucan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The whole course of treatment for vaginal thrush or penis thrush infection (candidal balanitis) is one capsule which you take by mouth. Swallow the capsule whole with a glass of water.

You can take your medicine with or without a meal at any time of day.

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.

How quickly will the treatment start to work?

Vaginal Thrush

Your condition should start to clear up within a few days - some women notice an improvement in one day.

If your condition does not clear up within a few days you should go back to your doctor.

Penis Thrush infection

Your condition should start to clear up within a few days but it may take up to a week.

If your condition has not cleared up after one week, you should go back to your doctor.

4. Possible side effect

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

A few people develop **allergic reactions** although serious allergic reactions are rare. If you get any of the following symptoms, **tell your doctor immediately**.

- Sudden wheezing, difficulty in breathing or tightness in 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).
- If you are an AIDS patient you are more likely to get severe skin reactions to drugs including **Diflucan**.

Very common side effects which may affect more than 1 person in 10 are listed below:

- feeling sick
- stomach discomfort
- diarrhoea

- wind
- rash
- headache

These undesirable effects are usually mild. If they cause you discomfort or are long lasting, check with your doctor or pharmacist.

You will find more about Diflucan on the back of this leaflet.

Other side effects

- itching
- being sick
- seizure
- lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- high blood levels of cholesterol, fats or salt
- liver damage and yellowing of the skin and eyes (Jaundice)
- hair loss
- dizziness
- altered sense of taste
- change in heart rate or rhythm
- insomnia (difficulty in sleeping)
- somnolence (feeling sleepy)
- myalgia (muscle pain)
- fatigue
- vertigo

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Diflucan

- Keep out of the reach and sight of children
- Do not store above 30°C.
- Do not use Diflucan after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

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.

6. Further information

What Diflucan contains

- The active substance is 150 mg fluconazole.
- The other ingredients are:

<i>Colouring agent:</i>
- Titanium dioxide (E171)
- Patent blue V (E131)
<i>Other inactive ingredients:</i>
- Colloidal silicon dioxide
- Gelatin (capsule shell)
- Lactose
- Magnesium stearate
- Maize starch
- Sodium Lauryl sulphate

The black printing ink used on the capsule shells contains: shellac, black iron oxide (E172), n-butyl alcohol, purified water, propylene glycol, industrial methylated spirits and isopropyl alcohol or alternatively shellac 24-27, black iron oxide (E172), dehydrated alcohol, purified water, propylene glycol, nbutyl alcohol, isopropyl alcohol, strong ammonia solution and potassium hydroxide.

What Diflucan 150 mg capsules look like and contents of the pack.

- Diflucan 150 mg capsules are light turquoise blue (cap and body), containing a white powder. They have “FLU 150” and “PFIZER” printed on them.
- Diflucan 150 comes in a blister pack containing one capsule.

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This leaflet was last approved in: February 2011

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