

Package leaflet: Information for the user
Diflazole 150 mg Capsules, hard

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 question, ask your doctor or pharmacist.
- 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet, See section 4.

What is in this leaflet

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

1. What Diflazole is and what it is used for

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

Diflazole 150 mg Capsules, hard is used in adults to treat infections caused by fungi. The most common cause of fungal infections is a yeast called *Candida*.

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

2. What you need to know before you take Diflazole

Do not take Diflazole

- If you are allergic 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 pimozide (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 Diflazole

- 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)

Ketoconazole is known to cause adrenal insufficiency (a condition in which the adrenal glands do not produce adequate amounts of steroid hormones), and this could also although rarely seen be applicable to fluconazole.

Children

Although this medicine is for adults it can be used in adolescents (from 12 to 17 years old) if treatment is essential and no suitable alternative exists, and should be taken in the same way as for adults.

Other medicines and Diflazole

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 Diflazole 150 mg Capsules, hard (see section: "Do not take Diflazole"). There are some medicines that may interact with Diflazole. Make sure your doctor knows if you are taking any of the following medicines:

- rifampicin or rifabutin (antibiotics for infections)
- 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 (indanedione, 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 felodipine and losartan (for hypertension- high blood pressure)
- 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)
- vitamin A (nutritional supplement)
- hydrochlorothiazide (a 'water pill')
- amiodarone (used for treating heart problems)

Diflazole with food and drink

You can take your medicine with or without a meal.

Pregnancy and breast-feeding

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.

Driving and using machines

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

Diflazole Capsules, hard contains Lactose and Sunset yellow (E110)

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

The capsule also contains sunset yellow (E110), which can cause an allergic-like reaction, including asthma, in some people. This is more common in people who are allergic to aspirin.

3. How to take Diflazole

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

Swallow the capsule whole with a glass of water.

Adults

150 mg as a single dose.

Doctors sometimes prescribe different doses to these. Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Elderly

The usual adult dose should be given.

Patients with kidney problems

The usual adult dose should be given.

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.

If you take more Diflazole than you should

Taking too many capsules at once 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 Diflazole

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 though, do not take the dose that you missed.

If you stop taking Diflazole

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.

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 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).

Diflazole 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 Diflazole 150 mg Capsules, hard 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, which may affect up to 1 in 10 people, are listed below:

- Headache
- Stomach discomfort
- Diarrhoea
- Feeling sick
- Vomiting
- Increases in blood tests of liver function
- Rash

Uncommon side effects which may affect up to 1 in 100 people are listed below:

- 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 which may affect up to 1 in 1,000 people are listed below:

- 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

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diflazole

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Diflazole contains

The active substance is fluconazole.

The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinized maize starch, colloidal anhydrous silica, magnesium stearate and sodium laurilsulfate. The capsule shell contains titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110) and gelatin.

What Diflazole looks like and contents of the pack

The name of your medicine is Diflazole 150 mg Capsules, hard. This is a hard yellow capsule. Diflazole 150 mg Capsules, hard is available in a blister pack containing 1 hard capsule.

Marketing Authorisation Holder:

Teva Pharma B.V.
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer:
Pharmathen S.A
Dervenakion 6
Pallini 15351
Attikis
Greece

Remember: this treatment is for YOU. Only a doctor can prescribe it for you. Never give it to others.

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