

Package leaflet: Information for the user

Diflazon 150 mg hard capsules fluconazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told to you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

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

1. What Diflazon is and what it is used for

Diflazon is in a group of medicines called “antifungals”. The active agent is fluconazole.

Diflazon is used to treat infections caused by fungi. The most common cause of fungal infections is a yeast called *Candida*.

Vaginal yeast infections caused by *Candida* are characterised by itching, swelling and redness of the cervical mucous membrane and granular vaginal discharge that adheres to mucous membrane. The symptoms are similar with foreskin yeast infection (balanitis) (itching, redness and sometimes soreness).

This medication is used to treat genital yeast infection – vaginal (women) or foreskin (men).

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before taking Diflazon

Do not take Diflazon:

- if you are allergic to fluconazole or any of the other ingredients of this medicine (listed in section 6). 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

Ask your doctor, pharmacist or nurse for advice before using Diflazon.

Talk to your doctor:

- 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 have ever had a severe rash or flaking of the skin, blisters and/or mouth ulcers after taking Diflazon.
- 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 the fungal infection does not improve, other antifungal treatment may be needed.

Serious skin reactions, including eosinophilia and systemic symptoms, have been reported during treatment with Diflazon. If you notice any of the symptoms of a serious skin reaction mentioned in section 4, stop taking Diflazon and contact your doctor immediately.

Other medicines and Diflazon

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 pimozide (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 Diflazon (see section: “Do not take Diflazon”).

There are some medicines that may interact with Diflazon.

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 (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 or high blood pressure);
- olaparib (used to treat ovarian cancer);
- hydrochlorothiazide (a diuretic and for hypotension);
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplanted tissue or organ 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 to treat rheumatoid arthritis);
- vitamin A (nutritional supplement);
- ivacaftor (used for treating cystic fibrosis);
- amiodarone (used for treating uneven heartbeats – arrhythmias);
- ibrutinib (used to treat blood cancer).

Diflazon with food and drink

You can take this 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.

Do not take Diflazon if you are pregnant, think you may be pregnant, or are trying to become pregnant, or if you are breast-feeding, unless your doctor tells you otherwise.

Use of fluconazole during the first trimester of pregnancy may increase the risk of miscarriage.

Taking low-dose fluconazole during the first trimester may slightly increase the risk of having a child with a musculoskeletal defect.

Breastfeeding can be continued after a single dose of 200 mg fluconazole or less.

Driving and using machines

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

Diflazon contains lactose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Diflazon

Always take this medicine exactly as your doctor or pharmacist 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.

If the pain has not subsided or increases, contact a doctor within 3 days after the treatment.

If the yeast infection re-emerges more than twice within a period of 6 months after the treatment, contact a doctor.

Elderly

The usual adult dose should be given.

Patients with kidney problems

The usual adult dose should be given.

How quick is the effect?

Vaginal yeast infection

Your condition will improve within a couple of days; some women will get better in a day. If your condition does not improve within a couple of days, you need to contact a doctor.

Foreskin yeast infection

Your condition will improve within a couple of days or up to a week. If your condition does not improve within a week, you need to contact a doctor.

If you take more Diflazon 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 Diflazon

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 you have any further questions on the use of this product, 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 experience 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).

Stop taking Diflazon and contact your doctor immediately if you notice any of the following symptoms:

- extensive rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic symptoms, or hypersensitivity syndrome).

Diflazon 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)

Diflazon may damage your adrenal glands and production of steroid hormones. The signs of adrenal gland problems include:

- tiredness
- muscle weakness
- loss of appetite
- weight loss
- abdominal pain.

If any of these occur, stop taking Diflazon 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)

- headache
- stomach discomfort, diarrhoea, feeling sick, vomiting
- liver blood tests abnormal values
- rash.

Uncommon side effects (may affect up to 1 in 100 people)

- 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)

- lower than normal white blood cells that help defend against infections and thrombocytes that help to stop bleeding
- red or purple discoloration of the skin which may be caused by low thrombocytes 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.

Side effects of unknown frequency (cannot be estimated from the available data):

- a hypersensitivity reaction with skin rash, fever, swelling of the glands, an increase in certain types of white blood cells (eosinophilia) and inflammation of the internal organs (liver, lungs, heart, kidneys and colon) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diflazon

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

Do not store above 25 °C.

Do not use this medicine after the expiry date which is stated on the label 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 package and other information

What Diflazon contains

- The active agent is fluconazole. One capsule contains 150 mg of fluconazole.
- Other excipients are: lactose monohydrate, maize starch, colloidal silica anhydrous, magnesium stearate and sodium laurilsulfate inside the capsule and gelatine, titanium oxide (E171) and blue dye V (E131) in the shell of the capsule.
See section 2 “Diflazon contains lactose and sodium”.

What Diflazon looks like and contents of the pack

Light-blue capsule shell and the capsule with capsule cap is filled with a white or almost white powder.

The capsules are available by 1 in a blister package inside a carton box. Each box has 1 blister with 1 capsule.

Marketing authorization holder and manufacturer

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

KRKA, d.d., Novo mesto Estonian branch
Pärnu mnt 141
11314 Tallinn
Tel: 6671658

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