



Adizole 150 mg capsules

Fluconazole

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 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What **Adizole** is and what it is used for

Adizole belongs to a group of antifungal drugs. The active substance is fluconazole.

Adizole is used to treat infections caused by fungi and can also be used to protect against candida infection.

The most common cause of fungal infections is yeast called *Candida*.

Adults

This medication may be prescribed to you by your doctor to treat the following types of fungal infections:

- Cryptococcal meningitis - a fungal infection in the brain;
- * *Coccidioidomycosis* - a disease of the bronchi and lungs;
- * Infections caused by fungi called *Candida*, which are located in the circulation, body organs (eg. heart, lungs) or urinary tract;
- * Mucosal Candidiasis - infection affecting the lining of the mouth, throat and denture sore mouth;
- * Genital thrush - an infection of the vagina or penis;
- * Skin infections, e. fungal foot infections (athlete's foot), fungal infections of the skin, known as ringworm, fungal infections of the groin infection of nails.

You may be applied **Adizole** in the following cases:

- * to stop the recurrence of fungal infection of the mucous membranes;
- * to limit the recurrence of vaginal candidiasis;
- * to not catch an infection caused by *Candida* (if your immune system is weak or does not work properly).

Adolescents

This medication may be prescribed to you by your doctor to treat the following types of fungal infections:

- Fungi on mucous membranes - infection affecting the lining of the mouth, throat;
- Infections caused by fungi called *Candida*, which are located in the circulation, the body organs (eg. heart, lungs) or urinary tract;
- Cryptococcal meningitis - a fungal infection of the brain.

Adizole can be given to you:

- * To not develop an infection caused by *Candida* (if your immune system is weak or does not work properly);
- * To prevent the recurrence of cryptococcal meningitis.

2. What you need to know before you take **Adizole**

Do not take **Adizole**:

- * 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 and difficulty 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 mental illness);
- * if you are taking quinidine (used for heart arrhythmia);
- * if you are taking erythromycin (antibiotic to treat infections);
- * if you are taking amiodarone (used for treating uneven heartbeats 'arrhythmias')

Warnings and precautions

Talk to your doctor or pharmacist before using **Adizole** if you:

- * have liver or kidney problems;
- * suffer from heart disease, including heart rhythm problems;
- * have abnormal levels of potassium, calcium or magnesium in the blood;
- * get severe skin reactions (itching, reddening of the skin or difficulty 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)

Other medicines and **Adizole**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Tell your doctor immediately if you are taking astemizole, terfenadine (an antihistamine for treating allergies) or cisapride (for stomach upsets) or pimozone (used to treat mental illness) or quinidine (used to treat cardiac arrhythmia) or erythromycin (an antibiotic for treatment infections) as these medicines should be taken with **Adizole** (see section "Do not use **Adizole**").

Some medicines may interact with **Adizole**. Please tell your doctor if you are taking any of the following medications:

- * rifampinil or rifabutin (antibiotics for infections);
- * alfentanil, fentanyl (pain medication);
- * amitriptyline, nortriptyline (antidepressants);
- * amphotericin B, voriconazole (an antifungal medicine);
- * drugs that prevent the blood from clotting (warfarin or similar drugs);
- * benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or anxiety;
- * carbamazepine, phenytoin (to treat seizures);
- * nifedimin, isradipine, amlodipine, felodipine and losartan (for treatment of hypertension - high blood pressure);
- * ciclosporin, everolimus, sirolimus or tacrolimus (to prevent organ rejection after transplants);
- * cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar drugs) used in the treatment of cancer;
- * halofantrine (in the treatment of malaria);
- * statins (atorvastatin, simvastatin and fluvastatin or similar medicines) used to lower cholesterol;
- * methadone (used for pain);
- * celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (a non-steroidal anti-inflammatory drug (NSAIDs));
- * oral contraceptives;
- * prednisone (steroid);
- * zidovudine, also known as AZT; saquinavir (used in patients with HIV);
- * antidiabetic drugs such as chlorpropamide, glibenclamide, glipizide or tolbutamide;
- * theophylline (used for asthma);
- * vitamin A (food additive);
- * ivacaftor (applied in the treatment mucoviscidosis).

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Adizole with food and drink

You can take this medicine with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, you think you may be pregnant or planning to become pregnant, ask your doctor or pharmacist before taking this medicine.

You should not take **Adizole** while pregnant or breast-feeding, unless your doctor has told you.

Driving and using machines

When driving or operating machinery it must be borne in mind that may occur dizziness or fainting.

Adizole contains lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this product.

3. How to take **Adizole**

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

Swallow the capsules whole with a glass of water. It is best to take the capsules at the same time each day.

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

Disease	Dosage
For the treatment of cryptococcal meningitis	400 mg first day, then 200 mg to 400 mg once daily for 6 to 8 weeks or longer if necessary. Sometimes the dosage was increased to 800 mg
To prevent recurrence of cryptococcal meningitis	200 mg once daily until you are told to stop treatment

Disease	Dosage
For the treatment of candidiodermomycosis	200 mg to 400 mg once daily for 11 to 24 months or longer if necessary. In some cases the dose may be increased to 800 mg
Fungal infection of internal organs caused by Candida	800 mg first day, then 400 mg once daily until you are told to stop treatment
For treatment of mucosal infections of the mouth and throat and inflammation of the mouth due to dental procedures	200 mg to 400 mg on the first day, then 100 mg to 200 mg until you are told to stop treatment
Fungal infections of the mucous membranes - the dosage depends on the localization of the infection	50 to 400 mg once daily 7 to 30 days until you are told to stop treatment
To prevent infections of the mucous membranes of the mouth and throat	100 mg to 200 mg once daily or 200 mg thrice a week while you are at risk of developing infection
For the treatment of genital candidiasis	150 mg as a single dose
In order to reduce recurrence of vaginal candidiasis	150 mg every third day a total of 3 doses (day 1, 4 and 7), and then once a week for 6 months while you are at risk
Fungal infections of the skin and nails	Depending on the site of infection 50 mg once daily, 150 mg once weekly, 300 mg to 400 mg once weekly for 1 to 4 weeks (for fungal infections of the foot (foot of an athlete) can last up to 6 weeks for infections nails - while infected fingernail grow again)
To not develop an infection caused by Candida (if your immune system is weak or does not work properly)	200 to 400 mg once daily while you are at risk of developing infection

Adolescents 12 to 17 years

Follow the dose prescribed by your doctor (dosage for children or adults).

Disease	Dosage
Fungal infections of the mucous membranes and the throat infections caused by Candida - dose depends on the severity and site of infection	3 mg per kg of body weight (first day can be administered 6 mg per kg of body weight)
Cryptococcal meningitis or fungal infections of the internal organs caused by Candida	6 mg to 12 mg per kg body weight
In order not to develop child infection caused by Candida (if the immune system is weak or does not work properly)	3 mg to 12 mg per kg body weight

Elderly

Apply the usual dose for adults unless you have kidney problems.

Patients with kidney problems

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

If you take more Adizole than you should

Taking too many capsules at once may make you unwell. Please immediately contact your doctor or go to the nearest hospital. Symptoms of overdose may make you hear, see and think things that are not real (hallucinations and paranoid behavior). It is appropriate to use symptomatic treatment (supportive measures and gastric lavage if necessary).

If you forget to take Adizole

Do not take a double dose to make up the missed dose. If you forget to take a dose, take it as soon as you remember. If it is 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.

Some people develop **allergic reactions** although serious allergic reactions occur rarely. If you experience any of these symptoms, **tell your doctor**:

- * sudden shortness of breath, difficulty breathing or chest tightness;
- * swelling of eyelids, face or lips;
- * itching, redness of the skin or itchy red spots;
- * skin rash;

- * severe skin reactions such as blistering rash (which can affect the mouth and tongue).

Adizole may affect your liver. Signs of liver damage include:

- * fatigue;
 - * loss of appetite;
 - * vomiting;
 - * yellowing of your skin or the whites of the eyes.
- Adizole may affect your adrenal glands and the levels of steroid hormones produced. The signs of adrenal problems include:
- tiredness
 - muscle weakness
 - loss of appetite
 - weight loss
 - abdominal pain

If you experience any of these side effects, stop taking Adizole and tell your doctor immediately.

Other adverse reactions:

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

Common side effects (may affect up to 1 to 10 people) are:

- * headache;
- * stomach discomfort, diarrhea, feeling sick, vomiting;
- * elevated liver function tests;
- * rash.

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

- * lowering the number of red blood cells, which can cause paleness, cause weakness or shortness of breath;
- * decreased appetite;
- * insomnia, drowsiness;
- * fainting, sleepiness, dizziness, tingling, pricking or numbness, changes in taste;
- * constipation, indigestion, flatulence, dry mouth;
- * muscle pain;
- * liver damage and yellowing of the skin and eyes (jaundice);
- * rash, blisters, itching, excessive sweating;
- * fatigue, malaise, fever.

Rare side effects (may affect up to 1 to 1000 people) are:

- * low white blood cells that protect the body from infections and blood cells that help to stop bleeding;
- * red or violet color on the skin, which may be caused by a decrease in platelet counts, changes in the other blood cells;
- * changes in blood parameters (high cholesterol levels in blood, fat);
- * decreases in potassium in the blood;
- * tremors;
- * abnormal electrocardiogram (ECG) changes in heart rate;
- * liver failure;
- * allergic reactions (sometimes severe), including extensive blistering rash and skin peeling, swelling of the lips or face;
- * hair loss.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Adizole

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 carton. The expiry date refers to the last day of that month.

Keep in the original package at temperature below 30° C.

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 Adizole contain

The active substance is fluconazole.

Each capsule contains 150 mg fluconazole.

The other ingredients are lactose monohydrate, cellulose, microcrystalline, maize starch, sodium lauryl sulfate, silica, colloidal anhydrous and magnesium stearate.

What Adizole looks like and contents of the pack

Adizole 150 mg capsules are gelatin capsules of size "0" with white body and green cap.

They are supplied in packs containing 1 or 7 capsules, but these may not all be available in your country.

Shelf life

3 years from the manufacture date.

Marketing Authorisation Holder and Manufacturer:

Adipharm EAD

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Sofia 1700, Bulgaria – EU

www.adipharm.com for the information of our patients

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