

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Fluconazole Teva 150 mg

Capsules

Composition:

Each capsule contains:
Fluconazole 150 mg

For a list of inactive and allergenic ingredients in this medicine, see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Adults:

Fluconazole Teva 150 mg is intended for treating the following types of fungal infections:

- Cryptococcal meningitis – a fungal infection in the brain.
- Coccidioidomycosis – a disease of the bronchopulmonary system.
- Infections caused by *Candida* and originating in the blood stream, body organs (for example heart, lungs) or urinary tract.
- Oral thrush – infection affecting the mucosa of the oral cavity, throat and dentures.
- Genital thrush – infection of the vagina or penis.
- Skin fungus, including athlete's foot, fungus in the groin area, tinea versicolor, nail fungus and skin inflammations caused by *Candida*.

The medicine is also intended for:

- Preventing cryptococcal meningitis from coming back.
- Preventing oral thrush from coming back.
- Reducing the recurrence of vaginal thrush.
- Preventing you from getting an infection caused by *Candida* (if your immune system is weak and not working properly).

Children and adolescents (0 to 17 years old):

Fluconazole Teva 150 mg is intended for treating the following types of fungal infections:

- Oral thrush – infection affecting the mucosa of the oral cavity and throat.
- Infections caused by *Candida* and originating in the blood stream, body organs (for example heart, lungs) or urinary tract.
- Cryptococcal meningitis – a fungal infection in the brain.

This medicine is also intended for:

- Preventing you from getting an infection caused by *Candida* (if your immune system is weak and not working properly).
- Preventing cryptococcal meningitis from coming back.

Therapeutic group:

Azole antifungals.

Fluconazole Teva 150 mg belongs to a group of medicines called "antifungals". The active ingredient in it is fluconazole. Fluconazole is intended for use in infections caused by fungi and also to prevent infections caused by *Candida*. The most common cause of fungal infections is a type of yeast called *Candida*.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (fluconazole), to other medicines you have taken to treat fungal infections, or to any of the ingredients in this medicine (listed in section 6). The symptoms may include itching, reddening of the skin or difficulty in breathing.
- You are taking astemizole, terfenadine (antihistamines for treating allergy).
- You are taking cisapride (for treating stomach upsets).
- You are taking pimozone (for treating mental illness).
- You are taking quinidine (for treating heart arrhythmias).
- You are taking erythromycin (an antibiotic for treating infections).

Special warnings about using this medicine

Before using this medicine, tell your doctor if:

- You have liver or kidney problems.
- You have heart disease, including heart rhythm problems.
- You have abnormal levels of potassium, calcium, or magnesium in your blood.
- You develop severe skin reactions (itching, reddening of the skin, or difficulty in breathing).
- You develop symptoms of 'adrenal insufficiency'. In this condition, the adrenal glands do not produce adequate amounts of hormones such as cortisol (chronic, or long lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain).
- You have ever developed a severe skin rash or skin peeling, blistering and/ or mouth sores after taking fluconazole.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with fluconazole treatment. Stop taking Fluconazole Teva 150 mg and seek medical attention immediately if you notice any of the symptoms related to the serious skin reactions described in section 4.

Tell your doctor if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Children and adolescents:

There are other fluconazole-containing preparations that can be given to children.

Drug interactions:

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Tell your doctor immediately if you are taking astemizole, terfenadine (an antihistamine for treating allergy), or cisapride (for stomach upsets), or pimozone (for treating mental illness), or quinidine (for treating arrhythmias), or erythromycin (an antibiotic for treating infections), as these medicines must not be taken with Fluconazole Teva 150 mg (see section 2, 'Do not use this medicine if').

Certain medicines can interact with Fluconazole Teva 150 mg. Make sure your doctor knows whether you are taking any of the following medicines:

- Rifampicin or rifabutin (antibiotics for treating infections).
- Alfentanil, fentanyl (used for anesthesia).
- Amitriptyline, nortriptyline (for treating depression).
- Amphotericin B, voriconazole (antifungals).
- Blood thinning medicines to prevent blood clots (warfarin or similar medicines).
- Benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety.
- Carbamazepine and phenytoin (for treating seizures).
- Nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan (for treating hypertension).
- Olaparib (for treating ovarian cancer).
- Cyclosporine, everolimus, sirolimus, tacrolimus (to prevent rejection of transplanted organs).
- Cyclophosphamide or vincristine, vinblastine or similar medicines for treating cancer.
- Halofantrine (for treating malaria).
- Statins (atorvastatin, simvastatin, fluvastatin or similar medicines) for reducing high cholesterol levels.
- Methadone (for treating pain).
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (nonsteroidal anti-inflammatory drugs (NSAIDs)).
- Oral contraceptive pills.
- Prednisone (a steroid).
- Zidovudine, saquinavir (for treating HIV-infected patients).
- Anti-diabetes medicines such as chlorpropamide, glibenclamide, glipizide or tolbutamide.
- Theophylline (for treating asthma).
- Tofacitinib (for treating rheumatoid arthritis).
- Tolvaptan (for the treatment of hyponatremia [low sodium in the blood] or to slow kidney function decline).
- Vitamin A (a nutritional supplement).
- Ivacaftor (for treating cystic fibrosis).
- Amiodarone (for treating heart arrhythmias).
- Hydrochlorothiazide (a diuretic).
- Ibrutinib (for treating blood cancer).

Using this medicine and food:

This medicine can be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you are pregnant or are planning to have a baby, consult your doctor before taking this medicine. Do not take Fluconazole Teva 150 mg if you are pregnant, think you may be pregnant or are planning to become pregnant, unless your doctor has told you otherwise. Fluconazole taken during the first trimester of pregnancy may increase the risk of miscarriage. Fluconazole taken at low doses during the first trimester may slightly increase the risk of a baby being born with birth defects affecting the bones and/or muscles. You can continue breastfeeding after taking a single dose of up to 150 mg of fluconazole.

Do not breastfeed if you are taking a repeated dose of Fluconazole Teva 150 mg.

Driving and using machines:

Using this medicine can sometimes cause dizziness or seizures and therefore requires caution when driving a vehicle and operating machines.

Important information about some of this medicine's ingredients:

Fluconazole Teva 150 mg contains **lactose**. Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to certain sugars (including lactose) consult the doctor before taking this medicine.

Fluconazole Teva 150 mg contains less than 1 millimole of sodium (23 mg) per capsule, so it is considered 'sodium free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this preparation.

Only your doctor will determine your dose and how you should take this medicine. The recommended dose generally depends on the type of infection that you have.

Elderly:

A similar dose to that generally given to adults, unless you have kidney problems.

Patients with kidney problems:

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

Do not exceed the recommended dose!

How to take this medicine:

Swallow the capsule whole with a glass of water.

It is advisable to take the capsule at a set time every day.

Do not open the capsule and release its contents, because the effect of this form of administration has not been tested.

If you have accidentally taken a higher dose:

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. Taking an overdose may cause you to feel unwell.

Symptoms of an overdose may include hearing, seeing or feeling things that do not exist including unreal thoughts (hallucinations and paranoid behavior). You may need treatment in such situations.

If you forget to take this medicine at the scheduled time:

Do not take a double dose to make up for the forgotten dose. If you forget to take your dose at the scheduled time, take it as soon as you remember. If it is almost time for your next dose, do not take the forgotten dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Fluconazole Teva 150 mg may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking Fluconazole Teva 150 mg and contact a doctor immediately if you notice any of the following symptoms:

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

Some people develop **allergic reactions**, although serious allergic reactions are rare. If you develop any side effect, contact your doctor or pharmacist. This includes any side effect not listed in this leaflet.

Contact a doctor immediately in case of:

- Difficulty in breathing, sudden wheezing or tightness in the chest.
- Swelling of the eyelids, face or lips.
- Itching all over the body, reddening of the skin or itchy red areas.
- Skin rash.
- Severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue).

The medicine may affect your liver. Symptoms of liver problems include:

- Tiredness.
- Loss of appetite.
- Vomiting.
- Yellowing of the skin or the eyes (jaundice).

If you experience any of these symptoms, stop using the medicine and **contact your doctor immediately**.

Other side effects:

Common side effects (affect 1-10 in 100 users):

- Headache.
- Abdominal discomfort, diarrhea, vomiting, nausea.
- Increase in level of liver enzymes in the blood.
- Rash.

Uncommon side effects (affect 1-10 in 1,000 users):

- Reduction in number of red blood cells, which could cause pale skin, weakness, or breathing difficulties.
- Decreased appetite.
- Insomnia, feeling drowsy.
- Seizures, dizziness, sensation of spinning, sensation of tingling, pricking or numbness, changes in sense of taste.
- Constipation, difficult digestion, flatulence, dry mouth.
- Muscle pain.
- Liver damage and yellowing of the skin or eyes (jaundice).
- Wheals, blistering of the skin (hives), itching, increased sweating.
- Tiredness, general feeling of being unwell, fever.

Rare side effects (affect 1-10 in 10,000 users):

- Reduction in number of white blood cells that help deal with infections and in the number of other blood cells that help stop bleeding.
- Red or purple discoloration of the skin which may be caused by a low platelet count and other blood cell changes.
- Blood chemistry changes (high blood levels of cholesterol, fats).
- Low levels of potassium in the blood.
- Shaking.
- Abnormal electrocardiogram (ECG), changes in heart rhythm.
- Liver failure.
- Allergic reactions (sometimes severe), including the appearance of a widespread rash with skin blisters and skin peeling, severe skin reactions, swelling of the lips or face.
- Hair loss.

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- Hypersensitivity reaction with skin rash, fever, swollen glands, an increase in a type of white blood cells (eosinophilia), and inflammation of internal organs (liver, lungs, heart, kidneys, and large intestine) (DRESS).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

Store in a dry place, below 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, maize starch, gelatin, magnesium stearate, titanium dioxide (E171), sodium laurilsulfate, silica colloidal anhydrous, brilliant blue FCF (E133).

What the medicine looks like and contents of the pack:

A hard gelatin capsule, filled with a white to yellowish white homogeneous powder. The body and cap of the capsule are an opaque light blue.

Pack size: 1, 6 capsules.

Not all pack sizes may be marketed.

Name and address of registration holder and manufacturer:

Teva Israel Ltd.,

124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in January 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 138.70.31385

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