

**Patient Leaflet According to the Pharmacists' Regulations (Preparations) –
1986**

This medicine is sold with a doctor's prescription only

**Flucanол 50, Flucanол 100, Flucanол 150, Flucanол 200
Capsules**

Active ingredient:

Each **Flucanол 50** capsule contains: fluconazole 50 mg

Each **Flucanол 100** capsule contains: fluconazole 100 mg

Each **Flucanол 150** capsule contains: fluconazole 150 mg

Each **Flucanол 200** capsule contains: fluconazole 200 mg

For the list of the additional ingredients, see section 6.

See also 'Important information about some of the medicine's ingredients' in section 2.

Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their disease is similar to yours.

1. What is the medicine intended for?

Adults

The medicine 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 (e.g., heart, lungs) or urinary tract
- Oral thrush – infection affecting the oral cavity mucous, throat and dentures
- Genital thrush – infection of the vagina or penis
- Skin fungus, including athlete's foot, fungus in the groin area, pityriasis versicolor, nail fungus and skin inflammations caused by Candida.

The medicine is also intended for:

- Preventing cryptococcal meningitis recurrence
- Preventing oral thrush recurrence
- 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)

The medicine is intended for treating the following types of fungal infections:

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

The 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 recurring cryptococcal meningitis

Therapeutic group:

Anti-fungal from the azole group.

The medicine belongs to a group of medicines called “anti-fungals”. The active substance in it is fluconazole. Fluconazole is intended for use in infections caused by fungi and also for the prevention of infections caused by Candida. The most common cause of fungal infections is a type of yeast called Candida.

2. Before using the medicine**Do not use the 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 additional ingredients the medicine contains (for the list of the additional ingredients, see section 6). Allergic symptoms can include itching, skin redness or difficulty in breathing.
- You are taking astemizole, terfenadine (antihistamines for treating allergy).
- You are taking cisapride (for treating stomach upsets).
- You are taking pimozide (for treating mental illness).
- You are taking quinidine (for treating heart rhythm disturbances-arrhythmia).
- You are taking erythromycin (an antibiotic for treating infections).

Special warnings regarding the use of this medicine:**Before (and during) the treatment with Flucanor, tell your doctor if:**

- You have liver or kidney problems.
- You suffer from heart disease, including heart rhythm problems.
- You have abnormal levels of potassium, calcium or magnesium in the blood.
- You develop severe skin reactions - itching, skin redness or breathing difficulty.
- You develop symptoms of ‘adrenal insufficiency’. In this condition, the adrenal glands do not produce adequate amounts of hormones such as cortisol. The symptoms may include chronic or long term fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain.
- You have 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 Flucanor and seek medical attention immediately if you notice any of the symptoms related to serious skin reactions as described in section 4.

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

Children and adolescents: there are other preparations containing fluconazole that enable administration to children.

Drug interactions:

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

Tell your doctor immediately if you are taking the following medicines: astemizole, terfenadine (antihistamines for treating allergy), cisapride (for treating stomach upsets), pimozide (for treating mental illness), quinidine (for treating arrhythmia), erythromycin (an antibiotic for treating infections), as these medicines must not be taken during treatment with Flucanол (see section: 'Do not use the medicine if').

There are certain medicines that could interact with Flucanол. Make sure your doctor knows if you are taking any of the following medicines:

- Rifampicin, rifabutin (antibiotics for treating infections).
- Alfentanil, fentanyl, methadone (opioids used inter alia as anesthetics, painkillers).
- Amitriptyline, nortriptyline (for treating depression).
- 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 as an anti-anxiety.
- Carbamazepine, phenytoin (for treating seizures).
- Nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan (for treating hypertension).
- Olaparib (for treating ovarian cancer).
- Ciclosporin, everolimus, sirolimus, tacrolimus (to prevent organ transplant rejection).
- Cyclophosphamide, vincristine, vinblastine or similar medicines for treating cancer.
- Halofantrine (for treating malaria).
- Statins (atorvastatin, simvastatin, fluvastatin or similar medicines) for reducing high cholesterol levels.
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (nonsteroidal anti-inflammatory drugs-NSAIDs).
- Contraceptive pills.
- Prednisone (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 levels of sodium in the blood] or to slow kidney function decline).
- Vitamin A (a nutritional supplement).
- Ivacaftor (for treating cystic fibrosis).
- Amiodarone (for treating heart arrhythmia).
- Hydrochlorothiazide (a diuretic).
- Ibrutinib (for the treatment of blood cancer).

Use of the medicine and food

The medicine can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you are pregnant or are planning a pregnancy, consult your doctor before taking this medicine.

- Do not take the medicine if you are pregnant, think you are pregnant or are planning a pregnancy, unless your doctor has instructed you otherwise. Taking fluconazole during the first trimester of pregnancy may increase the risk of miscarriage. Taking fluconazole at low doses during the first trimester may slightly increase the risk that the baby will be born with birth defects affecting the bones and/or muscles.
- You can continue breastfeeding after taking a single dose of Flucanor at a dosage of up to 150 mg.
- Do not breastfeed if you are taking a repeated dose of Flucanor.

Driving and use of machinery:

The use of this medicine can sometimes cause dizziness or seizures and therefore requires caution when driving a vehicle and operating machinery.

Important information about some of the medicine's ingredients

The medicine contains lactose. If you suffer from an intolerance to certain sugars, inform your doctor before taking this medicine (see section 6).

3. How to use this medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the treatment regimen with the medicine. The dosage and treatment regimen will be determined by the doctor only.

The standard dosage generally depends on the type of infection you have.

Elderly: A dosage similar to that generally given to adults unless you have kidney problems.

Patients with kidney problems: Your doctor may change your dosage, dependent on your kidney function.

Do not exceed the recommended dose!

Do not chew! Swallow the capsule with water.

You can open the capsule and distribute its contents on a small amount of food or drink and swallow.

There are other preparations containing fluconazole that enable administration to children.

If you accidentally took a higher dosage: if you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or a hospital's emergency room, and bring the package of the medicine 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 in reality, including unrealistic thoughts (hallucinations and paranoid behavior). You may need treatment in such situations.

If you forgot to take this medicine at the required time

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

Adhere to the treatment as recommended by your doctor.

Even if there is an improvement in your health condition, do not stop the treatment with the medicine without consulting a doctor.

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

If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, use of Flucanor may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop taking the medicine and contact your 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 syndrome (DRESS), or drug hypersensitivity syndrome).

Some people develop **allergic reactions**, however 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.

Stop treatment and contact a doctor immediately in case of:

- Breathing difficulties, sudden wheezing in your breathing, 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 blisters (may affect the mouth and tongue).

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

- Fatigue.
- 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**.

Additional side effects (including frequencies):

Common side effects (appear in 1-10 users out of 100):

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

Uncommon side effects (appear in 1-10 users out of 1,000):

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

Rare side effects (appear in 1-10 users out of 10,000):

- Decrease in number of white blood cells that help deal with infections and in a number of other blood cells that help stop bleeding.
- Change in skin color to red or purple which may be caused by a low platelet count and other changes in the blood cells.
- Chemical changes in the blood (high levels of cholesterol, fats in the blood).
- Low levels of potassium in the blood.
- Shaking.
- Abnormal 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 (effects whose frequency has not yet been determined):

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

If a side effect appears, if any of the side effects worsens, or when you suffer from a side effect not mentioned in the leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C.

6. Additional information

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

Lactose, maize starch, magnesium stearate, sodium lauryl sulphate, colloidal silica, titanium dioxide, gelatin.

Flucanол 50 capsules also contain: Yellow iron oxide (E172), indigo carmine (E132)

Flucanол 100 and **Flucanол 150** capsules also contain: Patent Blue V (E131)

Each **Flucanол 50** capsule contains about 50 mg lactose.

Each **Flucanол 100** capsule contains about 100 mg lactose.

Each **Flucanол 150** capsule contains about 150 mg lactose.

Each **Flucanол 200** capsule contains about 200 mg lactose.

What does the medicine look like and what does the package contain?

Flucanол 50: white-green capsules. In every package there is a blister of 7 capsules.

Flucanол 100: white-light blue capsules. In every package there is a blister of 7 capsules.

Flucanол 150: light blue capsules. In every package there is a blister of 1 capsule.

Flucanол 200: white capsules. In every package there is a blister of 7 capsules.

Manufacturer and registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health:

Flucanол 50: 1283630643

Flucanол 100: 1283730644

Flucanол 150: 1283830645

Flucanол 200: 1283930646

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