

Package leaflet: Information for the patient

Flunazol 50 mg hard capsules

Flunazol 150 mg hard capsules

Flunazol 50 mg / 5ml powder for oral suspension

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.

What is in this leaflet

- What Flunazol is and what it is used for
- What you need to know before you take Flunazol
- How to take Flunazol
- Possible side effects
- How to store Flunazol
- Contents of the pack and other information

1. What Flunazol is and what it is used for

This medicine contains the active substance fluconazole. It belongs to a group of medicines called “antifungals”.

Flunazol is used to treat infections caused by fungi and may also be used to stop you from getting a candidal infection. The most common cause of fungal infections is a yeast called Candida.

Adults:

You might be given this medicine by your doctor to treat 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 found in the blood stream, body organs (e.g. heart, lungs) or urinary tract
- Mucosal thrush: Infection affecting the lining of the mouth, throat and denture sore mouth

- Genital thrush: Infection of the vagina or penis
- Skin infections (e.g. athlete's foot, ringworm, jock itch, nail infection).

You might also be given Flunazol to:

- Stop cryptococcal meningitis from coming back

- Stop mucosal thrush from coming back

- Reduce recurrence of vaginal thrush

- Stop 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)

You might be given this medicine by your doctor to treat the following types of fungal infections:

- Mucosal thrush : infection affecting the lining of the mouth, throat

- Infections caused by Candida and found in the blood stream, body organs (e.g. heart, lungs) or urinary tract

- Cryptococcal meningitis: A fungal infection in the brain

You might also be given Flunazol to:

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

2. What you need to know before you take Flunazol

Do not take Flunazol:

- If you are allergic (hypersensitive) 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 Flunazol.

Take special care with Flunazol:

- 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).

Other medicines and Flunazol:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

There are some medicines that may interact with Flunazol. 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 (antifungal); 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, felodipine and losartan (for hypertension-high blood pressure); ciclosporin, everolimus , sirolimus or tacrolimus (to prevent transplant rejection); cyclosporinamide, 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; prednisolone (steroid); zidovudine, also known as AZT; saquinavir (used in HIV-infected patients); medicines for diabetes such as chlorpropamide, glibenclamide, glicipide or tolbutamide; theophylline (used to control asthma); vitamin A (nutritional supplement).

Flunazol with food and drinks:

This medicine can be taken with or without food.

Pregnancy and breast-feeding:

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding.

You should not take Flunazol while you are pregnant or breast-feeding unless your doctor has told you to.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines:

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

Important information about some of the ingredients of Flunazol:

- Flunazol 50 mg and 150 mg hard capsules contain lactose

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

- Flunazol 50 mg / 5 ml powder for oral suspension contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Flunazol

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

Taking this medicine:

- Flunazol 50 mg and 150 mg hard capsules:

• Swallow the capsule whole with a glass of water.

• It is best to take your capsules at the same time each day.

- Flunazol 50mg / 5ml powder for oral suspension:

• Instructions to make up the suspension:

1. Tap the closed bottle to loosen the powder.

2. Add a small quantity of still water and shake the closed bottle vigorously.

3. Add water up to the level marked on the bottle (this corresponds to adding 24 ml of water).

4. Shake well for one to two minutes to obtain a well mixed suspension.

5. Write the expiry date of the reconstituted suspension on the bottle label (the shelf life of the reconstituted suspension is 14 days). Any unused suspension should not be used after this date.

• Shake the closed bottle of the suspension every time before using it

• A measuring spoon is provided to deliver 5 ml of suspension, equivalent to 50 mg of fluconazole.

• Where doses of less than 5 ml are required, a suitable measuring device should be used. Dilution is not appropriate.

The usual doses of this medicine for different infections are below:

Adults:

Condition

To treat cryptococcal meningitis

To stop cryptococcal meningitis from coming back

To treat coccidioidomycosis

To treat mucosal infections affecting the lining of mouth, throat and denture sore mouth

To treat internal fungal infections caused by Candida

To treat mucosal infections affecting the lining of mouth, throat and denture sore mouth

To treat mucosal thrush – dose depends on where the infection is located

To stop mucosal infections affecting the lining of mouth, throat

To treat genital thrush

To reduce recurrence of vaginal thrush

To treat fungal skin and nail infections

To stop you from getting an infection caused by Candida (if your immune system is weak and not working properly)

Adolescents from 12 to 17 years old:

Follow the dose prescribed by your doctor (either adults or children posology).

Children over 4 weeks of age to 11 years old:

The maximum dose for children is 400 mg daily

The dose will be based on the child’s weight in kilograms.

Condition

Mucosal thrush and throat infections caused by Candida – dose and duration depend on the severity of the infection and on where the infection is located

Cryptococcal meningitis or internal fungal infections caused by Candida

To stop children from getting an infection caused by Candida (if their immune system is not working properly)

Children 0 to 4 weeks of age:

Use in children of 3 to 4 weeks of age:

The same dose as above but given once every 2 days. The maximum dose is 12 mg per kg of body weight every 48 hours.

Dose

400 mg on the first day then 200 mg to 400 mg once daily for 6 to 8 weeks or longer if needed. Sometimes doses are increased up to 800 mg

200 mg once daily until you are told to stop

200 mg to 400 mg once daily from 11 months for up to 24 months or longer if needed. Sometimes doses are increased up to 800 mg

800 mg on the first day then 400 mg once daily until you are told to stop

200 mg to 400 mg on the first day then 100 mg to 200 mg until you are told to stop

50 mg to 400 mg once daily for 7 to 30 days until you are told to stop

100 mg to 200 mg once daily, or 200 mg 3 times a week, while you are at risk of getting an infection

150 mg as a single dose

150 mg every third day for a total of 3 doses (day 1, 4 and 7) and then once a week for 6 months while you are at risk of getting an infection

Depending on the site of the infection 50 mg once daily, 150 mg once weekly, 300 to 400 mg once weekly for 1 to 4 weeks (Athlete’s foot may be up to 6 weeks, for nail infection treatment until infected nail is replaced)

200 mg to 400 mg once daily while you are at risk of getting an infection

You should check with your doctor or pharmacist if you are not sure.

Elderly:

The usual adult dose should be given unless you have kidney problems.

Patients with kidney problems:

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

If you take more Flunazol than you should

Taking too much of this medicine may make you unwell. Contact your doctor or go to your nearest hospital 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 Flunazol

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, 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

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).

Flunazol 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 Flunazol and tell your doctor immediately.

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 include:
Headache; stomach discomfort, diarrhea, feeling sick, vomiting; increase in blood tests of liver function; rash.

Uncommon side effects include:

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 include:

Lower than normal white blood cells and platelets; 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.

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 Flunazol

- 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 blister, bottle and the outer packaging. The expiry date refers to the last day of that month.

- Flunazol capsules: Store below 30°C.

- Flunazol oral suspension: Store dry powder below 30˚ C. Do not refrigerate. Once reconstituted with water, store the suspension between 5°C and 30°C. Do not freeze. The shelf-life of the reconstituted suspension is 14 days. Keep the bottle tightly closed.

- Keep away from light and humidity.

- Do not use this medicine if you notice visible signs of deterioration.

- Do not throw away any medicines via wastewater.

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 Flunazol contains

- The active substance is fluconazole.

- Flunazol 50 mg and 150 mg hard capsules other ingredients are: lactose, sodium lauryl sulfate, sodium croscarmellose, magnesium stearate. The capsule shell contains gelatine, indigotine and titanium dioxide.

- Flunazol 50 mg / 5 ml powder for oral suspension other ingredients are: sucrose, citric acid anhydrous, sodium citrate anhydrous, sodium saccharin, sodium benzoate, natural orange flavour, titanium dioxide.

What Flunazol looks like and contents of the pack

- Flunazol 50 mg hard capsules: Boxes containing 10 blue and white capsules.

Each hard capsule contains 50 mg of fluconazole.

- Flunazol 150 mg hard capsules: Boxes containing 1 blue and white capsule

Each hard capsule contains 150 mg of fluconazole.

- Flunazol 50 mg / 5ml powder for oral suspension: Dry white to off-white powder

After adding water to the powder an orange flavored suspension containing the equivalent of 10 mg of fluconazole per ml is produced.

The mixture of powder and water makes 35 ml of suspension. A 5 ml measuring spoon is provided to measure the correct dose.

Marketing Authorisation Holder and Manufacturer

Pharmaline, sal – Lebanon

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Contact us: pharmaline@maligroup.com

Reg. No. for Flunazol 50 mg hard capsules: 236407/98

Reg. No. for Flunazol 150 mg hard capsules: 236406/98

Reg. No. for Flunazol 50 mg / 5 ml oral suspension: 195342/04

This is a medicament

• A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

• Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.

• The doctor and the pharmacist are experts in medicine, its benefits and risks.

• Do not by yourself interrupt the period of treatment prescribed for you.

• Do not repeat the same prescription without consulting your doctor.

Council of Arab Health Ministers

The Council of Arab Pharmacists

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