

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

FUNGOCAP 150 mg and 200 mg capsules, hard fluconazole

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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1. WHAT FUNGOCAP IS AND WHAT IT IS USED FOR

Fungocap belongs to the group of antifungal medicines. The active substance is fluconazole.

Fungocap is used for the treatment of infections, caused by fungi and it can also be used to prevent you from candidosis.

Most commonly, fungal infections are caused by yeasts, called *Candida*.

Adults

This medicine may be prescribed for you by your doctor for the treatment of the following types of fungal infections:

- Cryptococcal meningitis – a fungal infection of the brain
- Coccidioidomycosis – a disease of the bronchi and lungs
- Infections, caused by fungi called *Candida*, which are localised in the blood flow, internal organs (for example, heart, lungs) or urinary system.
- Mucosal candidosis – an infection affecting the mucosal lining of the mouth and throat, and resulting from dental manipulations.
- Genital candidosis – an infection of the vagina or the penis.
- Skin infections, for example, fungal infections of the foot (an athlete's foot), fungal infections of the skin known as trichophytosis, fungal infections of the groin, infections of the nails.

Fungocap may be also administered in the following cases:

- To prevent the re-occurrence of cryptococcal meningitis.
- To prevent the re-occurrence of fungal infection of the mucosal lining.
- To limit the re-occurrence of vaginal candidosis.
- To prevent you from developing an infection, caused by *Candida* (if your immune system is weak or does not work properly).

Children and adolescents (0 to 17 years of age)

This medicine may be prescribed for you by your doctor for the treatment of the following types of fungal infections:

- Mucosal candidosis – an infection affecting the mucosal lining of the mouth and throat.

- Infections, caused by fungi called *Candida*, which are localised in the blood flow, internal organs (for example, heart, lungs) or urinary system.
- Cryptococcal meningitis – a fungal infection of the brain.

Fungocap may be also administered:

- To prevent you from developing an infection, caused by *Candida* (if your immune system is weak or does not work properly).
- To prevent the re-occurrence of cryptococcal meningitis.

2. BEFORE YOU TAKE FUNGOCAP

Do not take Fungocap

- if you are allergic (hypersensitive) to fluconazole, other medicines that you are taking for the treatment of fungal infection or to any of the other ingredients of Fungocap. The symptoms may include itching, redness of the skin or difficulty in breathing.
- if you are taking astemizole, terfenadine (antihistamine medicines for allergy)
- if you are taking cisapride (used for upset stomach)
- if you are taking pimozide (used for psychiatric diseases)
- if you are taking quinidine (used for cardiac arrhythmia)
- if you are taking erythromycin (an antibiotic for the treatment of infections).

Take special care with Fungocap

Please tell your doctor:

- if you have liver or kidney problems
- if you suffer from a heart disease, including rhythm disorders
- if you have abnormal blood levels of potassium, calcium or magnesium
- if you are experiencing severe skin reactions (itching, redness of the skin or difficulty in breathing)

Taking other medicines

Please tell your doctor if you are taking astemizole, terfenadine (antihistamine medicines for the treatment of allergy) or cisapride (used for upset stomach), or pimozide (used for the treatment of psychiatric diseases), or quinidine (used for treatment of cardiac arrhythmia), or erythromycin (an antibiotic for the treatment of infections), since these medicines should not be simultaneously taken with Fungocap (see section “Do not take Fungocap”).

Some medicines may interact with Fungocap. Please tell your doctor if you are taking some of the following medicines:

- rifampicin or rifabutin (antibiotics for the treatment of infections)
- alfentanil, fentanyl (pain-killers)
- amitriptylene, nortriptylene (antidepressants)
- amphotericin B, voriconazole (an antifungal medicine)
- medicines that prevent blood clotting (warfarin or similar medicines)
- benzodiazepines (midazolam, triazolam or similar medicines), used to help you falling asleep or for anxiety
- carbamazepine, phenytoin (for the treatment of seizures)
- nifedipine, isradipine, amlodipine, felodipine and losartan (for the treatment of hypertension/high blood pressure)
- ciclosporin, everolimus, sirolimus or tacrolimus (for the prevention of organ transplant rejection)
- cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar medicines) used for the treatment of cancer
- halofantrine (for the treatment of malaria)
- statins (atorvastatin, simvastatin and fluvastatin or similar medicines) used for the lowering of cholesterol

- methadone (used for pain)
- celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (non-steroidal anti-inflammatory drug (NSAID))
- oral contraceptives
- prednisone (a steroid)
- zidovudine, known as AZT; saquinavir (administered to HIV-patients)
- medicines for diabetes, such as chlorpropamide, glibenclamide or tolbutamide
- theophylline (used for asthma)
- vitamin A (a nutritional supplement)

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

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, planning to get pregnant or breast-feeding. You should not take Fungocap whilst you are pregnant or breast-feeding unless your doctor has told you to.

Ask your doctor for advice before taking any medicine.

Driving and using machines

When driving or using machines, you should take into consideration that dizziness or a syncope may occur.

Important information about some of the ingredients of Fungocap

If your doctor has told you that you have intolerance to some sugars, ask your doctor for advice before you start taking this product.

3. HOW TO TAKE FUNGOCAP

Always take Fungocap exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

For the different types of infections, the usual dosages of this medicine are listed below:

Adults

Disease	Dosage
For the treatment of cryptococcal meningitis	400 mg on Day 1, after then 200 mg to 400 mg once daily for 6 to 8 weeks or longer, if needed. In some cases, the dosage may be increased to 800 mg.
For the prevention of re-occurrence of cryptococcal meningitis	200 mg once daily until you are told to stop the treatment.
For the treatment of coccidioidomycosis	200 mg to 400 mg once daily for 11 to 24 months or longer, if needed In some cases, the dosage may be increased to 800 mg.

Fungal infection of internal organs, caused by <i>Candida</i>	800 mg on Day 1, after then 400 mg once daily, until you are told to stop the treatment.
For the treatment of mucosal infections in the mouth, throat and inflammation of the mouth due to the use of a denture	200 mg to 400 mg on Day 1, after then 100 mg to 200 mg until you are told to stop the treatment.
Fungal infections of the mucosal lining – the dosage depends on localisation of the infection	50 to 400 mg once daily for 7 to 30 days, until you are told to stop the treatment.
For the prevention of mucosal infections in the mouth and throat	100 mg to 200 mg once daily or 200 mg 3 times weekly, until you are at a risk of developing infection.
For the treatment of genital candidosis	150 mg as a single dose
For limiting the re-occurrence of vaginal candidosis	150 mg every three days, total of 3 doses (on days 1, 4 and 7), after then once weekly for 6 months, until you are at a risk of developing infection.
Fungal infections of the skin and nails	Depending on the infected site, 50 mg once daily, 150 mg once weekly, 300 mg to 400 mg once weekly for 1 to 4 weeks (in fungal infection of the foot (an athlete's foot) the treatment may continue for up to 6 weeks, for nail infections, until a new nail grows back)
To prevent you from developing an infection, caused by <i>Candida</i> (if your immune system is weak or does not work properly).	200 to 400 mg once daily, until you are at a risk of developing infection.

Adolescents from 12 to 17 years of age

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

Children of up to 11 years of age

The maximum dose in children is 400 mg daily.

The dosage is based on the weight of the child in kilograms.

Disease	Daily dose
Fungal infections of the mucosal lining and infections of the throat, caused by <i>Candida</i> – the dosage depends on the severity and site of infection	3 mg per kg of the body weight (on Day 1, 6 mg per kg body weight may be administered)
Cryptococcal meningitis or fungal infection of internal organs, caused by <i>Candida</i>	6 mg to 12 mg per kg body weight
To prevent the child from developing an infection, caused by <i>Candida</i> (if the child's immune system is weak or does not work properly).	3 mg to 12 mg per kg body weight

Use in children of 0 to 4 weeks of age

Use in children of 3 to 4 weeks of age:

The dose is the same as the above described, but it is administered every 2 days. The maximum dose is 12 mg per kg body weight every 48 hours.

Use in children younger than 2 weeks of age:

The dose is the same as the above described, but it is administered every 3 days. The maximum dose is 12 mg per kg body weight every 72 hours.

Physicians may sometimes prescribe doses, other than the listed above. Always take Fungocap exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Elderly patients

The usual dose for adults is administered, unless you have any kidney problems.

Patients with kidney problems

Your doctor may change your dosage depending on your renal function.

If you take more Fungocap than you should

The intake of a number of capsules at the same time can make you feel ill. Please contact your doctor immediately or go to the nearest hospital.

The symptoms of overdose can make you hear, see and believe things that are not real (hallucinations and paranoid behaviour). The institution of symptomatic treatment (supportive measures and gastric lavage, if needed) is appropriate.

If you forget to take Fungocap

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 the time for your next dose, do not take the dose you have already missed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Fungocap 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 the following symptoms, **contact your doctor immediately**.

- sudden shortness of breath, difficulty in breathing or chest tightness
- swelling of the eyelids, face or lips
- itching of the whole body, redness of the skin or itching red spots
- skin rash
- severe skin reactions, such as rash with blisters (which may affect the mouth and tongue).

Fungocap may affect your liver. The signs of liver impairment may include:

- fatigue
- loss of appetite
- vomiting
- yellowing of the skin and the whites of the eyes

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

Other side effects:

In addition, if any of the 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 affecting 1 to 10 in 100 patients are listed below:

- headache
- stomach discomfort, diarrhoea, malaise, vomiting
- elevated liver functional test results
- rash

Uncommon side effects affecting 1 to 10 in 1,000 patients are listed below:

- reduction of the number of red blood cells, which may cause paleness, weakness or shortness of breath
- decreased appetite
- sleeplessness, sleepiness
- syncope, sleepiness, vertigo, numbness, tingling or stiffness, taste alterations
- constipation, indigestion, wind, dry mouth
- muscle pain
- liver impairment and yellowing of the skin and the eyes (jaundice)
- rash, blistering, itching, excessive sweating
- fatigue, malaise, fever

Rare side effects affecting 1 to 10 in 10,000 patients are listed below:

- reduction of the number of white blood cells, which prevent the body from infections and blood cells, which support discontinuation of bleeding
- red or purple colouring of the skin, which may be induced by reduction of the number of thrombocytes, changes in other blood cells
- changes in blood parameters (high blood cholesterol and lipid levels)
- reduced blood potassium levels
- tremor
- abnormal findings on the electrocardiogram (ECG), changes of the heart rhythm
- liver insufficiency
- allergic reactions (sometimes severe), including extensive rash with blisters and scaling of the skin, swelling of the lips or face
- hair loss.

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

5. HOW TO STORE FUNGOCAP

- Keep out of the reach and sight of children.
- Do not use Fungocap after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store below 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Fungocap capsules, hard contains

- The active substance is fluconazole.
Each hard capsule contains 150 and 200 mg fluconazole, respectively.
- The other ingredients are lactose monohydrate; starch, pregelatinised; silica, colloidal anhydrous; magnesium stearate.
Capsule shell – titanium dioxide (E 171), gelatine for the capsules of 150 mg and titanium dioxide (E 171), iron oxide, yellow (E 172), gelatine for the capsules of 200 mg.

What Fungocap hard capsules looks like and contents of the pack

Fungocap 150 mg capsules, hard

Number 1 hard gelatine capsules, body – white; cap – white.

Contents of the capsule: white to off-white powder.

Fungocap 200 mg capsules, hard

Number 0 hard gelatine capsules, body – pale yellow; cap – pale yellow.

Contents of the capsule: white to off-white powder.

The product is supplied in the following packs:

Blisters of transparent, colourless PVC/AL foil or transparent, colourless PVC/PVdC/AL foil and a patient leaflet, inserted in a carton.

Pack sizes:

Fungocap 150 mg capsules, hard

Packs of 1, 2, 3, 4 or 10 capsules.

- 1 blister of 1, 2, 3, 4 or 10 capsules in a carton.
- 4 blisters with 1 capsule each, in a carton.

Fungocap 200 mg capsules, hard:

Packs of 1, 7, 10, 20 or 30 capsules.

- 1 blister of 1, 7 or 10 capsules in a carton.
- 2 blisters of 10 capsules each, in a carton.
- 3 blisters of 10 capsules each, in a carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Antibiotic-Razgrad AD

Office 201, 68 “Aprilsko vastanie” Blvd,
Razgrad 7200

Manufacturer

Balkanpharma-Razgrad AD

68 “Aprilsko vastanie” Blvd,
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