

Package leaflet: Information for the user

Mycozal 50mg capsules

Mycozal 100mg capsules

Mycozal 150mg capsules

Mycozal 200mg 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Mycozal is and what it is used for

Mycozal is one of a group of medicines called “antifungals”. The active substance is fluconazole.

Mycozal 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 Mycozal 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 Mycozal 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 Mycozal

Do not take Mycozal if you

- are allergic 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
- are taking astemizole, terfenadine (antihistamine medicines for allergies)
- are taking cisapride (used for stomach upsets)
- are taking pimozide (used for treating mental illness)
- are taking quinidine (used for treating heart arrhythmia)
- are taking erythromycin (an antibiotic for treating infections)

Warnings and precautions

Talk to your doctor or pharmacist before taking Mycozal .

Tell your doctor if you

- have liver or kidney problems
- suffer from heart disease, including heart rhythm problems
- have abnormal levels of potassium, calcium or magnesium in your blood.

- develop severe skin reactions (itching, reddening of the skin or difficulty in breathing).
- 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 Mycozal

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

Tell your doctor **immediately** if you are taking astemizole, terfenadine (an antihistamine for treating allergies) or cisapride (used for stomach upsets) or pimozide (used for treating mental illness) or quinidine (used for treating heart arrhythmia) or erythromycin (an antibiotic for treating infections) as these should not be taken with Mycozal (see section: “Do not take Mycozal if you”).

There are some medicines that may interact with Mycozal . Make sure your doctor knows if you are taking any of the following medicines:

- amiodarone (used for treating uneven heartbeats ‘arrhythmias’)
- hydrochlorothiazide (a diuretic)
- rifampicin or rifabutin (antibiotics for infections)
- alfentanil, fentanyl (used as anaesthetic)
- amitriptyline, nortriptyline (used as anti-depressant)
- 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 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)
- cyclophosphamide, 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
- prednisone (steroid)
- zidovudine, also known as AZT; saquinavir (used in HIV-infected patients)
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- theophylline (used to control asthma)

- vitamin A (nutritional supplement)
- ivacaftor (used for treating cystic fibrosis)

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

Mycozal with food and drink

You can take your medicine with or without a meal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take Mycozal while you are pregnant unless your doctor has told you to.

You can continue breast-feeding after taking a single dose of Mycozal up to 200 mg.

You should not breast-feed if you are taking a repeated dose of Mycozal .

Driving and using machines

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

Mycozal contains lactose and Sunset yellow (E110)

Each Mycozal 50mg capsule, hard contains 16.6 mg lactose monohydrate.

Each Mycozal 100mg capsule, hard contains 33.2 mg lactose monohydrate.

Each Mycozal 150mg capsule, hard contains 49.8 mg lactose monohydrate.

Each Mycozal 200mg capsule, hard contains 66.4 mg lactose monohydrate.

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

Each Mycozal 150mg capsule, hard also contains the colouring agent Sunset yellow (E110) that may cause allergic reactions.

3. How to take Mycozal

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

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

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

Adults

Condition	Dose
To treat cryptococcal meningitis	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
To stop cryptococcal meningitis from coming back	200 mg once daily until you are told to stop
To treat coccidioidomycosis	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
To treat internal fungal infections caused by <i>Candida</i>	800 mg on the first day then 400 mg once daily until you are told to stop
To treat mucosal infections affecting the lining of mouth, throat and denture sore mouth	200 mg to 400 mg on the first day then 100 mg to 200 mg until you are told to stop
To treat mucosal thrush – dose depends on where the infection is located	50 mg to 400 mg once daily for 7 to 30 days until you are told to stop
To stop mucosal infections affecting the lining of mouth, throat	100 mg to 200 mg once daily, or 200 mg 3 times a week, while you are at risk of getting an infection
To treat genital thrush	150 mg as a single dose
To reduce recurrence of vaginal thrush	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
To treat fungal skin and nail infections	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)
To stop you from getting an infection caused by <i>Candida</i> (if your immune system is weak and not working properly)	200 mg to 400 mg once daily while you are at risk of getting an infection

Adolescents from 12 to 17 years old

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

Children 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	Daily dose
Mucosal thrush and throat infections caused by <i>Candida</i> – dose and duration depends on the severity of the infection and on where the infection is located	3 mg per kg of body weight (6 mg per kg of body weight might be given on the first day)
Cryptococcal meningitis or internal fungal infections caused by <i>Candida</i>	6 mg to 12 mg per kg of body weight
To stop children from getting an infection caused by <i>Candida</i> (if their immune system is not working properly)	3 mg to 12 mg per kg of body weight

Use in 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.

Use in children less than 2 weeks old:

The same dose as above but given once every 3 days. The maximum dose is 12 mg per kg of body weight every 72 hours.

Elderly

The recommended 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 Mycozal than you should

Taking too many capsules at once may make you unwell. Contact your doctor or your nearest hospital casualty department 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 Mycozal

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

Mycozal 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 Mycozal and **tell your doctor immediately**.

Other side effects:

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 (may affect up to 1 in 10 people) are:

- headache
- stomach discomfort, diarrhoea, feeling sick, vomiting
- increases in blood tests of liver function
- rash

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

- 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 (may affect up to 1 in 1,000 people) are:

- lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- 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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Pharmaceuticals Services

Ministry of Health

CY-1475, Nicosia

www.moh.gov.cy/phs

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mycozal

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 and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Mycozal contains

Mycozal 50mg capsules contain 50mg of fluconazole as active substance. The other excipients are lactose monohydrate, microcrystalline cellulose (E460), pregelatinized maize starch, colloidal silicon dioxide (E551), magnesium stearate (E470b) and sodium lauryl sulphate. The capsule shells contain titanium dioxide (E171), quinoline yellow (E104), iron oxide yellow (E172), patent blue V (E131) and gelatin.

Mycozal 100mg capsules contain 100mg of fluconazole as active substance. The other excipients are lactose monohydrate, microcrystalline cellulose (E460), pregelatinized maize starch, colloidal silicon dioxide (E551), magnesium stearate (E470b) and sodium lauryl sulphate. The capsule shells contain titanium dioxide (E171), iron oxide yellow (E172), and gelatin.

Mycozal 150mg capsules contain 150mg of fluconazole as active substance. The other excipients are lactose monohydrate, microcrystalline cellulose (E460), pregelatinized maize starch, colloidal silicon dioxide (E551), magnesium stearate (E470b) and sodium lauryl sulphate. The capsule shells contain titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110) and gelatin.

Mycozal 200mg capsules contain 200mg of fluconazole as active substance. The other excipients are lactose monohydrate, microcrystalline cellulose (E460), pregelatinized maize starch, colloidal silicon dioxide (E551), magnesium stearate (E470b) and sodium lauryl sulphate. The capsule shells contain titanium dioxide (E171) and gelatin.

What Mycozal 50mg, 100mg, 150mg, 200mg capsules look like and contents of the pack

Transparent PVC/Aluminium blister

Pack sizes:

Mycozal 50mg green and white capsules: 7, 10, 14, 20, 28, 30, 50 and 100 capsules

Mycozal 100mg buff capsules: 7, 10, 14, 20, 28, 50 and 100 capsules.

Mycozal 150mg yellow capsules: 1, 2 and 4 capsules.

Mycozal 200mg white capsules: 7, 10, 14, 20, 28, 50 and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sapiens Pharmaceuticals Ltd
P.O.Box 56351-3306
Limassol, Cyprus

Manufacturer

Pharmathen S.A.,
6 Dervenakion str,
15344 Pallini, Attiki,
Greece
Tel: 0030 210 66 65 067
Fax: 0030 210 66 66 749
Email: info@pharmathen.com

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Fluconazol Mylan 50/100/150/200 mg capsules

Cyprus: Mycozal 50/100/150/200 mg capsules

Estonia: Fluconazole ELVIM 50/150 mg capsules, hard

Finland: Canesoral 150 mg capsules

Greece: Stabilanol 200 mg capsules

Iceland: Fungyn 50/150/200 mg capsules

Latvia: Fluconazole ELVIM 50/150 mg capsules

Lithuania: Fluconazole ELVIM 50/150 mg capsules

Luxembourg: Fluconazole Mylan 50/100/150/200 mg capsules

Netherlands: Fluconazol Pharmathen 50/100/150/200 mg capsules