

## **Package leaflet: Information for the user**

**Fluconazole Milpharm 50 mg capsules, hard**  
**Fluconazole Milpharm 150 mg capsules, hard**  
**Fluconazole Milpharm 200 mg capsules, hard**  
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 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.

### **What is in this leaflet:**

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

### **1. What Fluconazole Milpharm is and what it is used for**

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

Fluconazole Milpharm 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 Fluconazole Milpharm 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 Fluconazole Milpharm 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 Fluconazole Milpharm**

### **Do not take Fluconazole Milpharm:**

- 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 using Fluconazole Milpharm

#### **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 Fluconazole Milpharm** 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 Fluconazole Milpharm (see section: "Do not take Fluconazole Milpharm if you").

There are some medicines that may interact with Fluconazole Milpharm. 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 (anti-fungal)
- medicines that thin the blood to prevent blood clots (warfarin, indanedione 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)
- amiodarone (used for treating uneven heartbeats 'arrhythmias')
- hydrochlorothiazide (used to treat fluid retention)

**Fluconazole Milpharm with food and drink and alcohol** You can take your medicine with or without a meal

**Pregnancy and breast-feeding and fertility**

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.

**Driving and using machines**

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

**Fluconazole Milpharm capsule contains lactose monohydrate**, a type of sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

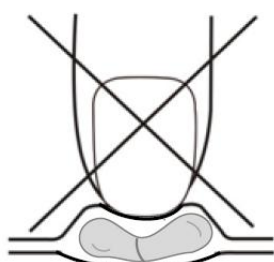
### 3. How to take Fluconazole Milpharm capsules

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

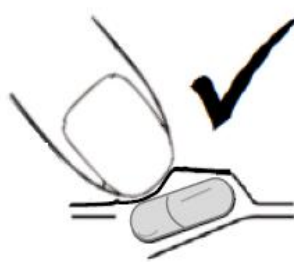
Swallow the capsule whole with a glass of water. It is best to take your capsules at the same time each day.

**Instructions to remove the capsule from blister pocket:**

Pushing the capsule pocket in its middle portion may cause deformation/ breakage of capsule as shown in Fig. A. In order to avoid such damage remove the capsule by pushing the capsule pocket at its edge as shown in Fig. B.



**Fig. A**



**Fig. B**

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

### Use in children and adolescents

#### 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.

Doctors sometimes prescribe different doses to these. Always take your medicine exactly as your doctor has told you. 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 Fluconazole Milpharm 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 Fluconazole Milpharm**

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).

Fluconazole Milpharm 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 Fluconazole Milpharm 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 which may affect up to 1 in 10 people are listed below:

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

Uncommon side effects which may affect up to 1 in 100 people are listed below:

- 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 which may affect up to 1 in 1000 people are listed below:

- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Fluconazole Milpharm**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Fluconazole Milpharm contains**

- The active substance is fluconazole.
- Each capsule contains 50 mg, 150 mg or 200 mg fluconazole.
- The other ingredients are lactose monohydrate, maize starch, sodium lauril sulfate, colloidal anhydrous silica and magnesium stearate.

The capsule shell contains titanium dioxide (E171), sodium lauril sulfate and gelatin.

The printing ink contains shellac, propylene glycol, yellow iron oxide.

### **What Fluconazole Milpharm looks like and contents of the pack**

#### ***Fluconazole Milpharm 50mg Capsules***

Size '4' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '95' on white to off-white opaque body with yellow ink.

#### ***Fluconazole Milpharm 150mg Capsules***

Size '1' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '97' on white to off-white opaque body with yellow ink.

#### ***Fluconazole Milpharm 200mg Capsules***

Size '0' hard gelatin capsule filled with white to off-white powder and imprinted with 'E' on white to off-white opaque cap and '98' on white to off-white opaque body with yellow ink.

Fluconazole Milpharm capsules are available in

#### **Clear PVC/PVDC-Aluminium blister**

Fluconazole Milpharm 50mg/150mg/200mg: 1, 2, 3, 4, 5, 6, 7, 10, 14, 20, 21, 28, 30, 50, 60, 90, 100 capsules

#### **HDPE Bottle**

Fluconazole Milpharm 50mg: 30 and 1000 capsules

Fluconazole Milpharm 200mg: 30 and 500 capsules

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Milpharm Limited

Ares, Odyssey Business Park

West End Road

South Ruislip HA4 6QD

United Kingdom

### **Manufacturer**

APL Swift Services (Malta) Limited

HF 26, Hal Far Industrial Estate, Hal Far

Birzebbugia, BBG 3000

Malta

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

Austria:	Fluconazol Aurobindo 50mg/ 100mg/ 150mg/ 200mg Hartkapseln
Czech Republic:	Fluconazol Aurobindo 50mg/ 100mg/ 150mg tvrdé tobolky
Denmark:	Fluconazol "Aurobindo"
Germany:	Fluconazol Aurobindo 50mg/ 100mg/ 150mg/ 200mg Hartkapseln
Greece:	Fluconazole Aurobindo 50mg/ 100mg/ 150mg καψάκια, σκληρά
Hungary:	Fluconazol Aurobindo 150mg kemény kapszula
Ireland:	Fluconazole Milpharm 50mg/ 150mg/ 200mg capsules, hard
Italy:	Fluconazolo Aurobindo 50mg/ 100mg/ 150mg/ 200mg capsule rigide
Netherlands:	Fluconazol Aurobindo 50mg/ 150mg/ 200mg, capsules

Poland:	Fluconazole Aurobindo
Portugal:	Fluconazol Aurobindo 50mg/ 100mg/ 150mg/ 200mg cápsulas duras
Romania:	Fluconazol Aurobindo 50mg/ 100mg/ 150mg capsule
Spain:	Fluconazol Aurobindo 50mg/ 100mg/ 150mg/ 200mg cápsulas duras
Sweden:	Fluconazol Aurobindo 50mg/ 100mg/ 150mg/ 200mg kapslar, hårda
United Kingdom:	Fluconazole 50mg/ 100mg/ 150mg/ 200mg capsules, hard

**This leaflet was last approved in 06/2016.**