

Fluconazole

MYLAN 2 mg/mL

100 mg /
50 mL

200 mg /
100 mL

400 mg /
200 mL

- 1 bag of 50 mL
solution for infusion
- or
- 1 bag of 100 mL
solution for infusion
- or
- 1 bag of 200 mL
solution for infusion
- IV intravenous infusion

 Mylan

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

It contains some important information for your treatment.

Keep this leaflet. You may need to read it again.

If you have any further questions, or if you have a doubt, ask your physician or pharmacist for more information.

You were personally prescribed this medicine. Never give it to someone else, even if the person has identical symptoms, as it may be harmful to him/her.

The active substance is: For 1 mL of solution for infusion

Fluconazole 2 mg

One 50 mL bag contains 100 mg of Fluconazole

One 100 mL bag contains 200 mg of Fluconazole.

One 200 mL bag contains 400 mg of Fluconazole.

The other ingredients are: sodium chloride, water for injections.

Excipients with well-known effects: sodium.

Benta S.A.L.,
Dbayeh - Lebanon



Under license from

Mylan S.A.S.

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What is Fluconazole Mylan 2 mg/mL, solution for infusion, and what it is used for?

This medicine is a solution for infusion, in 50 mL, 100 mL or 200 mL bags.

Box of 1 bag (200 mL) or box of 1 bag (100 mL) or box of 1 bag (50 mL).

This is an ANTIFUNGAL AGENT FOR SYSTEMIC USE.

(J: Anti-infectious)

It controls the development of microscopic fungi.

This medicine is indicated for the treatment of:

In adults:

- neuromeningeal cryptococcosis,
- systemic, oesophageal, and urinary candidiasis.

In infants and children:

- oropharyngeal candidiasis in immunodepressed patients,
- systemic, oesophageal, and urinary candidiasis,
- neuromeningeal cryptococcosis.

This medicine is also used to prevent sensitive Candida infections in adults with leukaemia and presenting a decrease in the number of white blood cells as a result of the treatment received.

Before you take Fluconazole Mylan 2 mg/mL, solution for infusion?



Do not take Fluconazole Mylan 2 mg/mL, solution for infusion:

- if you have a known allergy to fluconazole and to related substances (azole compounds),
- if you are pregnant or breastfeeding, unless otherwise directed by a physician,
- in combination with:
 - cisapride (a drug used for the treatment of gastroesophageal reflux),
 - pimozide (a drug used for the treatment of some mood disorders),
 - halofantrine (a drug used for the treatment of malaria).

Use Fluconazole Mylan 2 mg/mL, solution for infusion with care:

Women with child bearing potential are required to use a contraceptive method.



Warnings

Should you develop symptoms evocative of serious liver disorders (major asthenia, anorexia, persistent nausea, vomiting, jaundice), you must consult a physician.

If you already have had a skin reaction associated with Fluconazole or another azole compound intake, you should consult a physician as quickly as possible if bullous skin lesions develop.

This medicine contains 3.54 mg of sodium (i.e. 0.154 mmol) of sodium per mL of solution for injections: this should be taken into account by patients with a strict low-salt diet.



Pregnancy - Breast feeding

This medicine should not be used during pregnancy and while breastfeeding, unless otherwise directed by a physician.

Seek your physician's or chemist's advice before taking any medicine.

Listing of excipients with well-known effects: sodium.



Intake or use of other medicines

This medicine should not be used in combination with *cisapride* (a drug used for the treatment of gastroesophageal reflux), *pimozide* (a drug used for the treatment of some mood disorders) and *halofantrine* (a drug used for the treatment of malaria).

Please notify your physician or chemist if you take or have recently taken another medicine, even if this product was obtained without prescription.

How to use Fluconazole Mylan 2 mg/mL, solution for infusion?



Adult:

- *Cryptococcosis*: 400 mg/day for 6 to 8 weeks, then 200 mg/day (for life in patients with AIDS).
- *Œsophageal candidiasis*: 100 mg/day.
- *Urinary candidiasis*: 100 – 200 mg/day.
- *Systemic candidiasis*: 800 mg on the 1st day and 400 mg/day afterwards.
- *Candidiasis prophylaxis*: the recommended dosage is 400 mg per day in one daily dosage. *Fluconazole administration should start from the initiation of chemotherapy or graft conditioning. It should be continued for 7 days after the count of polynuclear neutrophils has increased above 1000/mm³ or for a longer period (up to 75 days).*

Child and infant:

- *oropharyngeal candidiasis in immunodepressed patients*: 3 mg/kg/day every 24 hours,
 - *systemic, Œsophageal, and urinary candidiasis*: 6-12 mg/kg/day every 24 hours,
 - *neuromeningeal cryptococcosis*: 6-12 mg/kg/day every 24 hours (for life in patients with AIDS).
- No dosage is suggested for premature infants, full-term newborn infants, and up to 28 days of life.

If you believe that the effect of Fluconazole Mylan 2 mg/mL, solution for infusion is too strong or too weak, consult your physician or chemist.



Intravenous infusion.

The duration of treatment depends on the clinical response and on the indication.

Instructions for use of the bag without infusion system

- Remove the bag from the overpack; use immediately after opening.
- Remove the protector from the infusion site.
- Connect the administration set to the bag.

It is a gravity administration: the infusion flow rate must be regularly verified during the infusion.

In any case, strictly abide by your physician's prescription.

If you have taken more Fluconazole Mylan 2 mg/mL, solution for infusion than you should have, seek immediate advice from your physician or chemist.

If you forgot to take Fluconazole Mylan 2 mg/mL, solution for infusion: never take a double dose in order to compensate for the dose you forgot to take.

Possible side effects

As with any medicine, Fluconazole mylan 2 mg/mL, solution for infusion may cause side effects:

Skin and gastrointestinal effects are the most common side effects.

- *Gastrointestinal side effects*: nausea, flatulence, abdominal pains, diarrhoeas.
- *Cutaneous and allergic side effects*: rashes, severe skin reactions, allergic reactions.

Some cases of hair loss, usually reversible, have been reported.

• *Systemic effects*: headaches.

- *Hepatic side effects*: increase of liver transaminases (liver enzymes) generally reversible after treatment is stopped, severe hepatic disorders.
- *Haematologic side effects*: leucopenias (insufficient amount of white blood cells in the blood); thrombopenias (abnormally low rate of platelets which are important elements for blood coagulation).

If you notice side effects, which are not mentioned in this package leaflet, please notify your physician or chemist.

How to store Fluconazole Mylan 2 mg/mL, solution for infusion?

Before opening: To be stored at a temperature not exceeding +30°C, do not refrigerate nor freeze.

After opening of the overpack: The product must be used immediately. If not used immediately, in use storage times and conditions after dilution and before use, are the responsibility of the user.

However, the physico-chemical stability has been demonstrated for 24 hours at a temperature of +25°C in the following infusion liquids:

- Glucose solution,
- Ringer's solution,
- Ringer Lactate's solution,
- Potassium chloride in glucose solution,
- Sodium bicarbonate.

Keep out of the reach and sight of children.

Do not use after the expiry date indicated on the box, bag.

The latest date at which this package leaflet was approved was: 07/2012

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
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists