

FLUKAS® 2 mg/ml solution for infusion Fluconazole

Read 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.
- You may have further questions, ask your doctor or 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. (See section 4).

What is in this leaflet?

- What is FLUKAS 2 mg/ml solution for infusion and in which case is it used?
 - How to take FLUKAS 2 mg/ml solution for infusion?
 - How to take FLUKAS 2 mg/ml solution for infusion?
 4. Possible side effects
 5. How to store FLUKAS 2 mg/ml solution for infusion?
 6. Content of the packaging and other information
- 1. WHAT IS FLUKAS 2 mg/ml solution for infusion AND IN WHICH CASE IS IT USED?**
- Fluconazole is an antimycotic for systemic use, triazole derivative - ATC Code: J02AC01. FLUKAS is one of a group of medicines called "antifungals". The active substance is fluconazole. FLUKAS is used to treat fungal infections and can also be used to prevent you from getting a *Candida* infection. The most common cause of fungal infections is a yeast called *Candida*.

Adults

Your doctor may prescribe this medicine for you to treat the following fungal infections:

- cryptococcal meningitis - cerebral fungal infection
- occidididomycosis - a disease of the bronchopulmonary system,
- Candida infections, found in the blood, infections of organs (e.g. heart, lungs) or urinary tract,
- mucoasal yeast infection - infection of the lining of the mouth, throat, and sores caused by dentures.

You may also receive FLUKAS to:

- avoid recurrence of cryptococcal meningitis,
- avoid the recurrence of the mucoasal yeast infection
- avoid developing a *Candida* infection (if your immune system is weakened and not working properly).

Newborns on term, infants, children and adolescents (0-17 years)

Your doctor may prescribe this medicine to treat the following types of fungal infections:

- mucoasal yeast infection - infection of the lining of the mouth, throat,
- Candida infections, found in the blood, infections of the organs (e.g. heart, lungs) or urinary tract,
- cryptococcal meningitis - fungal infection of the brain.

You may also receive FLUKAS to:

- avoid you from developing a *Candida* infection (if your immune system is weak and not working properly),
- avoid the recurrence of the mucoasal yeast infection

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUKAS 2 mg/ml solution for infusion?

Never take FLUKAS 2 mg/ml solution for infusion:

- if you are allergic to fluconazole, to other medicines you have taken to treat fungal infections or to any of the other components of this medicine, listed in section 6. Symptoms may be itching, redness of the skin, or difficulty breathing.
- if you are taking astemizole, terfenadine (antihistamine medicines used to treat allergies),
- if you are taking cisapride (used for upset stomach),
- if you are taking pimozide (used to treat mental problems),
- if you are taking quinidine (used to treat irregular heartbeats),
- if you are taking erythromycin (an antibiotic to treat infections).

Warnings and precautions

Talk to your doctor or pharmacist before taking FLUKAS 2 mg/ml solution for infusion.

- if you have liver or kidney problems,
- if you have heart disease, including heart rhythm disturbances,
- if you have abnormal levels of potassium, calcium or magnesium in your blood,
- if you develop severe skin reactions (itching, redness of the skin or difficulty breathing),
- if you develop signs of adrenal insufficiency, a disorder in which the adrenal glands produce insufficient amounts of certain steroid hormones such as cortisol (chronic or prolonged fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain).

Children and adolescents

Not applicable.

Other medicines and FLUKAS 2 mg/ml solution for infusion

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 to treat allergies) or cisapride (used to treat indigestion) (used to treat mental disorders) or quinidine (used to treat cardiac arrhythmias) or erythromycin (an antibiotic to treat infections) as these should not be taken with FLUKAS (see section "Do not take FLUKAS 2 mg/ml solution for infusion").

Other medicines may interact with FLUKAS. Be sure to tell your doctor if you are taking any of the following medicines:

- antifungal or rifabutin (antibiotics used to treat infections),
- alfentanil, fentanyl (used as anesthetics),
- amitriptyline, nortriptyline (used as antidepressants),
- anticholinergics B. voriconazole (antifungals),
- cardemazepine, phenytoin (used to treat seizures),
- nicloflupine, isradipine, amlodipine, verapamil, felodipine and losartan (for high blood pressure),
- clapiribin (used to treat ovarian cancer),
- ciclosporin, everolimus, sirolimus or tacrolimus (to prevent transplant rejection),
- cytostatics/chemotherapy, vinca alkaloids (vinorelbine, vinflastine or similar medicines) used to treat cancer,
- halofantril (used to treat malaria),
- clonidine (atovastatin, simvastatin and fluvastatin or similar medicines) used to reduce high cholesterol,
- methadone (used for pain),
- gabapentin, duloxetine, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (nonsteroidal anti-inflammatory drugs (NSAIDs)),

Other contraindications

- prednisone (corticosteroid),
- zidovudine, also known as AZT, zalcitabine (used in patients with HIV infection),
- anticholinergics such as chlorpromazine, gliclazide, glipizide or tolbutamide,
- theophylline (used to control asthma),
- tofacitinib (used to treat rheumatoid arthritis),
- gabapentin (an infection supplement),
- ivacaftor (used to treat cystic fibrosis),
- amiodarone (used to treat irregular heartbeat or arrhythmias),
- hydrochlorothiazide (a diuretic),
- brithinil (used to treat cancer of the blood).

FLUKAS 2 mg/ml solution for infusion with food and drinks

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning pregnancy, ask your doctor or pharmacist for advice before taking this medicine.

You should not take FLUKAS during pregnancy unless your doctor has told you to do so.

You can continue to breastfeed after taking a single dose of 150 mg of FLUKAS.

You should not breastfeed if you are taking a repeated dose of FLUKAS.

Driving and using machines

When driving vehicles or using machines, it should be considered that dizziness or epileptic seizures may occur.

FLUKAS 2 mg/ml solution for infusion contains sodium

This medicine contains 0.154 mmol sodium per ml. This should be considered in patients following a low sodium diet.

3. HOW TO TAKE FLUKAS 2 mg/ml solution for infusion?

General

This medicine will be given by your doctor or nurse as a slow injection (infusion) into your vein. FLUKAS is supplied as a solution. It will not need to be diluted later. More information for healthcare professionals is available at the end of this leaflet.

The recommended doses of this medicine for different infections are shown below. Ask your doctor or nurse for advice if you are not sure why you are taking FLUKAS.

Affection	Dosage
To treat cryptococcal meningitis	400 mg on the first day, then 200 to 400 mg once daily for 6 to 8 weeks or more if needed. Doses are sometimes increased up to 800 mg
To avoid the recurrence of cryptococcal meningitis	200 mg once a day until you are told to stop
To treat coccididomycosis	200 to 400 mg once a day for a period of 11 months to 24 months or more if necessary. Doses are sometimes increased up to 800 mg
To treat internal fungal infection caused by <i>Candida</i>	800 mg on the first day, then 400 mg once a day until you are told to stop
To treat infection of the lining of the mouth, throat and sores caused by dentures	200 mg to 400 mg on the first day, then 100 mg to 200 mg once a day until you are told to stop
To treat yeast infection of the mucous membrane - a disease depending on the site of the infection	50 to 400 mg once a day for 7 to 30 days until you are told to stop
To avoid recurrence of infection of the oral mucosa and throat	100 mg to 200 mg once a day or 200 mg 3 times a week for as long as you are at risk of developing an infection
To avoid developing a <i>Candida</i> infection (if your immune system is weakened and not working properly)	200-400 mg once a day for as long as you are at risk of developing an infection

Adolescents aged 12 to 17

Take the dosage indicated by your doctor (either the dosage for adults or the dosage for children).

Children up to 11 years old

The maximum dosage in children is 400 mg per day. The dosage will be based on the child's weight in kilograms.

Affection	Daily dose
Yeast infection of the mucous membrane and throat infections caused by <i>Candida</i> - a dose and duration depend on the severity of the infection and its location	3 mg per kg of body weight once a day (a dose of 6 mg per kg of body weight can be used on the first day)
Cryptococcal meningitis or internal fungal infections due to <i>Candida</i>	6 mg to 12 mg per kg of body weight once a day
To avoid recurrence of cryptococcal meningitis	6 mg per kg of body weight once a day
To prevent children from developing a <i>Candida</i> infection (if their immune system is weakened and not working properly)	3 mg to 12 mg per kg of body weight once a day

Children aged 0 to 4 weeks

Children aged 3 to 4 weeks:
Same dosage as above but every 2 days only. The maximum dosage is 12 mg per kg of body weight every 48 hours.
Children under 2 weeks of age:
Same dosage as above but every 3 days only. The maximum dosage is 12 mg per kg of body weight every 72 hours.

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 FLUKAS 2 mg/ml solution for infusion than you should

If you are concerned that you have received too much FLUKAS, talk to your doctor or nurse immediately. Symptoms of a possible overdose may be hearing, seeing, feeling, or thinking things that are not real (hallucinations and paranoid behavior).

If you forget to take FLUKAS 2 mg/ml solution for infusion

As this medicine will be given to you under strict medical supervision, it is unlikely that a dose will be missed. However, tell your doctor or pharmacist if you think a dose has been missed.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse for more information.

4. POSSIBLE SIDE EFFECTS

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse for more information.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A few people develop allergic reactions, but severe allergic reactions are rare. If you get any side effects talk to your doctor or pharmacist. This also applies to any side effect not mentioned in this leaflet. If you experience any of the following symptoms, tell your doctor immediately.

- sudden wheezing, difficulty breathing, or tightness in the chest,
- swelling of the eyelids, face or lips,
- red, itchy skin all over the body or itchy red spots,
- skin rash,
- severe skin reactions such as rash causing bubbles to form (which may affect the mouth and tongue).

FLUKAS can affect your liver. Signs of liver problems include:

- fatigue,
- loss of appetite,
- vomiting,
- yellowing of the skin or the whites of the eyes (jaundice)

If any of these signs occur, stop taking FLUKAS and tell your doctor immediately.

Other side effects:

In addition, if you experience any of the effects mentioned as serious or if you experience any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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

- headache,
 - upset stomach, diarrhea, nausea, vomiting,
 - increases in blood tests related to liver function,
 - rash.
- Uncommon side effects (may affect up to 1 in 100 people) are:
- reduction in the number of red blood cells which may make the skin pale and cause weakness or shortness of breath,
 - decreased appetite,
 - inability to sleep, feeling drowsy,
 - seizure, dizziness, spinning sensation, pins and needles, tingling or numbness, changes in the sensation of taste,
 - constipation, difficulty digesting, gas, dry mouth,
 - muscle pain,
 - liver damage and yellowing of the skin and eyes (jaundice),
 - papules, bubbles (bites), itching, increased sweating,
 - fatigue, generally feeling unwell, fever.
- Rare side effects (may affect up to 1 in 1,000 people) are:
- decrease in the number of white blood cells (blood cells that help fight infection) and platelets (blood cells that help stop bleeding),
 - red or purple discoloration of the skin which may be due to a low number of platelets or other changes in blood cells,
 - biochemical changes in the blood (high levels of cholesterol, fat in the blood),
 - low level of potassium in the blood,
 - abnormalities in the electrocardiogram (ECG), change in heart rate or rhythm,
 - Hepatic insufficiency,
 - allergic reactions (sometimes severe), including generalized bullous rash and peeling of the skin, severe skin reactions, sweating of the lips or face,
 - hair loss.

Unknown Side effects (frequency cannot be estimated from the available data) are:

- hypersensitivity reactions (itching, fever, appearance of an increase in one type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and colon) (Drug reaction or rash with eosinophilia and systemic symptoms (DRESS)).

Reporting side effects

If you get any side effects talk to your doctor, pharmacist, or nurse. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system : National center of pharmacovigilance.

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

5. HOW TO STORE FLUKAS 2 mg/ml solution for infusion?

Store at a temperature below 30 °C and Do not freeze.

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 package after EXP. The expiration date refers to the last day of that month.

After opening, the product should be used immediately. Any unused infusion should be discarded. This medicine is for single use only.

Do not use this medicine if you notice any visible particles or if the solution is not clear or discolored.

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

6. CONTENT OF THE PACKAGING AND OTHER INFORMATION

What FLUKAS 2 mg/ml solution for infusion contains

- the active substance is: fluconazole
- Each ml contains 2 mg of fluconazole.
- One 50 ml vial of solution for infusion contains 100 mg of fluconazole.
- One 100 ml vial of solution for infusion contains 200 mg of fluconazole.
- the other components are: Sodium chloride, water for injections, hydrochloric acid, or sodium hydroxide (for pH adjustment).

What does FLUKAS 2 mg/ml solution for infusion look like and content of the outer packaging

FLUKAS is a transparent, colorless solution without visible particles.

It comes either in the form of a glass bottle.

1 vial contains 50 ml solution for infusion.

1 vial contains 100 ml solution for infusion.

Marketing authorisation holder and manufacturer

Les Laboratoires SIELS
Road of Tunis - KM 7 - BP 206 8000 Nabeul - Tunisia
Tel : +216 72 235 006 / Fax : +216 72 235 016
E-mail : cont@slabomed.com
Supply and prescription Conditions: List I/ Table A
M.A.N°:
FLUKAS 100 - 9233371
FLUKAS 200 - 9233372
This leaflet was last revised 01/2021

THIS IS A MEDICINE

- A medicine is a product but not like the other.

- A medicine is a product that affects your health and its consumption without compliance to the prescription exposes you to danger.

- Strictly follow your doctor's prescription and directions for use, follow the advice of your pharmacist.

- Your doctor and pharmacist are familiar with the medicine, its indications, and contraindications.

- Do not stop treatment on your own initiative during the prescribed period.

- Do not take it again, do not increase the doses without consulting your doctor.

- *N'en reprenez pas, l'augmenter pas les doses sans consulter votre médecin.

Keep medicines out of the reach of children

Other

The following information is intended exclusively for healthcare professionals: The intravenous infusion should be administered at a rate not exceeding 10 ml / minute. FLUKAS is formulated in sodium chloride 9 mmol / l (0.9%) solution for infusion, each 200 mg dose (100 ml vial) containing 15 mmol Na⁺ and 15 mmol Cl⁻. Since FLUKAS is presented as a dilute solution in sodium chloride, care should be taken with the speed of administration of the solution in patients requiring sodium or water restriction.

Intravenous infusion of fluconazole is compatible with the following administration fluids:

- Dextrose 5% and 20%
- Ringer's solution
- Hartmann's solution
- Potassium chloride in dextrose
- Sodium bicarbonate 4.2% and 5%
- Aminoxyne 3.5%
- Sodium chloride 9 mg / ml (0.9%)
- Dialufex (6.56% intraperitoneal dialysis solution).

Fluconazole can be infused through an existing tubing with any of the fluids listed above. Although no specific incompatibilities have been observed, mixing with other drugs prior to infusion is not recommended.

The solution for infusion is for single use only.

From a microbiological point of view, the dilutions should be used immediately. If not used immediately, conditions and time before use are the responsibility of the user and should not exceed 24 hours at 2 °C to 8 °C, unless this dilution has been carried out under controlled and validated aseptic conditions.

Dilution should be performed under aseptic conditions. The solution should be visually inspected for particles and discoloration prior to administration. The solution should only be used if it is clear and free from particles.

Any unused product or waste must be disposed of in accordance with current regulations.