

Patient Information Leaflet for FLUCONAZOLE 2 mg/mL FRESENIUS

SCHEDULING STATUS: **S4**

FLUCONAZOLE 2 mg/mL FRESENIUS solution for infusion

Fluconazole

Sugar free.

Read all of this leaflet carefully before you are given FLUCONAZOLE FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What FLUCONAZOLE FRESENIUS is and what it is used for
2. What you need to know before you are given FLUCONAZOLE FRESENIUS
3. How FLUCONAZOLE FRESENIUS will be given
4. Possible side effects
5. How to store FLUCONAZOLE FRESENIUS
6. Contents of the pack and other information.

1. What FLUCONAZOLE FRESENIUS is and what it is used for

FLUCONAZOLE FRESENIUS is a medicine for the treatment and prevention of infections with fungi.

FLUCONAZOLE FRESENIUS belongs to a group of medicines active against infections with fungi, called imidazoles.

2. What you need to know before you are given FLUCONAZOLE FRESENIUS

FLUCONAZOLE FRESENIUS should not be given to you:

- if you are allergic (hypersensitive) to fluconazole, or other similar medicines such as ketoconazole and itraconazole or to any of the other ingredients of FLUCONAZOLE FRESENIUS (listed in section 6)
- in multiple doses of 400 mg per day or higher if you are also taking terfenadine (an antihistamine for allergies)
- if you are taking medicines known to affect your heart and that affect the way your body handles FLUCONAZOLE FRESENIUS, such as:
 - cisapride (used to treat heartburn and to lower stomach acid)
 - astemizole (an antihistamine for allergies)
 - erythromycin (an antibiotic)
 - pimozide (a so-called neuroleptic used to treat mental illness)
 - quinidine (used in the treatment of heart rhythm disorders)
- if you are pregnant or breastfeeding your infant.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with FLUCONAZOLE FRESENIUS:

- if you have *tinea capitis* (ringworm, a fungal infection of the scalp)
- if you have cryptococcosis (a fungal infection of the lungs or skin)
- if you have kidney disease
- if you have problems with your adrenal glands which produce certain hormones in the body
- if you have currently, or have previously had, problems with your liver
- if you have AIDS or have an infection that affects your whole body. If you have this, you may be more prone to serious skin reactions. Tell your doctor immediately if you develop skin rashes, hives or skin peeling

- if you are taking other medicines that work similar to FLUCONAZOLE FRESENIUS in the body (see “**Other medicines and FLUCONAZOLE FRESENIUS**”)
- if you have porphyria (a rare hereditary disease in which the blood pigment haemoglobin is abnormally metabolised)
- if you have heart disease including heart rhythm problems and/or electrolyte abnormalities such as low potassium levels in your blood.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with fluconazole treatment. Stop using FLUCONAZOLE FRESENIUS and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and FLUCONAZOLE FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The effect of treatment can be affected if FLUCONAZOLE FRESENIUS is used at the same time as certain other medicines. Please tell your doctor or other healthcare provider if you are taking or using any of the following medicines:

- **Abrocitinib** (used to treat atopic dermatitis, also known as atopic eczema).
- **Alfentanil** (a strong painkiller).
- **Amiodarone** (for irregular heartbeat).
- **Amitriptyline, nortriptyline** (used for the treatment of depression).
- **Amphotericin B** (used in the treatment of fungal infections).
- **Astemizole** (an antihistamine for allergies) (see “**FLUCONAZOLE FRESENIUS should not be given to you**”).
- **Benzodiazepines such** as midazolam or triazolam (certain sleeping pills).

- **Calcium channel blockers** such as nifedipine, isradipine, verapamil, nicardipine, amlodipine, felodipine (used in the treatment of heart rhythm disorders and high blood pressure).
- **Carbamazepine** (used in the treatment of epilepsy).
- **Celecoxib** (used in the treatment of inflammation).
- **Ciclosporin** (used in organ transplantation).
- **Cisapride** (used to treat heartburn and to lower stomach acid) (see “**FLUCONAZOLE FRESENIUS should not be given to you**”).
- **Cyclophosphamide** (used to treat several types of cancer).
- **Didanosine** (used in the treatment of HIV/AIDS).
- **Erythromycin** (an antibiotic) (see “**FLUCONAZOLE FRESENIUS should not be given to you**”).
- **Everolimus** (used to treat several types of cancer and in organ transplantation).
- **Fentanyl** (used for serious pain).
- **Halofantrine** (used to treat malaria).
- **HMG-CoA reductase inhibitors (so-called statins)** such as atorvastatin, simvastatin, fluvastatin (medicines that lower blood lipids).
- **Hydrochlorothiazide** (used to increase the flow of urine, a diuretic).
- **Ibrutinib** (used to treat certain types of cancer).
- **Isoniazid** (used in the treatment of tuberculosis (“TB”).
- **Ivacaftor** (alone or in combination with other medicines used for treating cystic fibrosis).
- **Losartan** (used in the treatment of high blood pressure).
- **Lurasidone** (used to treat schizophrenia).
- Medicines used to treat epilepsy in general.
- **Methadone** (a painkiller, opioid).
- **Midazolam, triazolam** (used to help you sleep or for anxiety).
- **Nevirapine** (for treatment of HIV/AIDS).

- **NSAIDs** (nonsteroidal anti-inflammatory drugs), such as flurbiprofen, ibuprofen, naproxen, lornoxicam, meloxicam, diclofenac (used to treat pain, inflammation and fever).
- **Olaparib** (used to treat certain types of cancer).
- **Oral contraceptives** (the pill – to prevent pregnancy).
- **Phenytoin** (used to control epilepsy).
- **Pimozide** (a so-called neuroleptic medicine, used to treat mental illness) (see “**FLUCONAZOLE FRESENIUS should not be given to you**”).
- **Prednisone** or other steroid therapies (cortisone-like medicines used in inflammation and organ transplants).
- **Quinidine** (a medicine used for irregular heartbeat) (see “**FLUCONAZOLE FRESENIUS should not be given to you**”).
- **Rifampicin or rifabutin** (used in the treatment of tuberculosis and other infections).
- **Saquinavir** (for treatment of HIV/AIDS).
- **Sirolimus** (used in organ transplantation).
- **Sulphonylureas** such as chlorpropamide, glibenclamide, glipizide or tolbutamide (used to control diabetes).
- **Tacrolimus** (used in organ transplantation).
- **Terfenadine** (an antihistamine for allergies) (see “**FLUCONAZOLE FRESENIUS should not be given to you**”).
- **Theophylline** (used to control asthma) and medicines related to theophylline called xanthine bases.
- **Tofacitinib** (used to treat certain types of arthritis, and ulcers in the colon).
- **Tolvaptan** (used to increase the flow of urine, a diuretic).
- **Trimetrexate** (used in the treatment of pneumonia).
- **Vinca alkaloids** such as vincristine and vinblastine (used to treat certain types of cancer).
- **Vitamin A** (to treat acne).
- **Voriconazole** (used in the treatment of fungal infections).

- **Warfarin** and other coumarin or indanedione type medicines (blood thinning medicines).
- **Zidovudine** (for treatment of HIV/AIDS).

Pregnancy and breastfeeding

FLUCONAZOLE FRESENIUS must not be given to you if you are pregnant or breastfeeding your baby (see “FLUCONAZOLE FRESENIUS should not be given to you”).

If you are planning to become pregnant, it is recommended to wait a week after a single dose of fluconazole before becoming pregnant.

For longer courses of treatment with fluconazole, talk to your doctor on the need for appropriate contraception during treatment which should continue for one week after the last dose.

FLUCONAZOLE FRESENIUS may increase the risk of miscarriage if given during the first or second trimester of pregnancy. Fluconazole taken at low doses during the first trimester may slightly increase the risk of a baby being born with birth defects affecting the heart, bones and/or muscles.

There have been reports of babies born with birth defects affecting the skull, ears, and bones of the thigh and elbow in women treated for three months or more with high doses (400-800 mg daily) of fluconazole for coccidioidomycosis. The link between fluconazole and these cases is not clear.

FLUCONAZOLE FRESENIUS is present in breastmilk; you should not receive FLUCONAZOLE FRESENIUS if you are breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before FLUCONAZOLE FRESENIUS is given to you.

Driving and using machines

It should be borne in mind that dizziness or fits can occasionally occur in people receiving FLUCONAZOLE FRESENIUS so care should be taken when driving or operating machinery (see “Possible side effects”).

It is not always possible to predict to what extent FLUCONAZOLE FRESENIUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which FLUCONAZOLE FRESENIUS affects them.

FLUCONAZOLE FRESENIUS contains sodium

FLUCONAZOLE FRESENIUS contains salt (sodium chloride).

If you are on a low sodium (salt) diet tell your doctor or other healthcare provider before they give you FLUCONAZOLE FRESENIUS.

FLUCONAZOLE FRESENIUS contains 3,5 mg sodium (main component of cooking/table salt) in each mL. This is equivalent to 0,175 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How FLUCONAZOLE FRESENIUS will be given

You will not be expected to give yourself FLUCONAZOLE FRESENIUS. It will be given to you by a person who is qualified to do so.

FLUCONAZOLE FRESENIUS will be administered to you via a drip (slow injection into a vein).

The dose will be determined by your doctor.

Treatment will normally continue until the infection has gone.

Patients with kidney problems

Your doctor will adjust the dose based on your kidney function.

Children

Your doctor will determine the dose in children.

If you receive more FLUCONAZOLE FRESENIUS than you should:

Since a healthcare provider will administer FLUCONAZOLE FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you are worried you have been given too much or have any questions about the dose talk to your doctor or other healthcare provider.

If you forget to receive FLUCONAZOLE FRESENIUS

Since a healthcare provider will administer FLUCONAZOLE FRESENIUS, it is unlikely that the dose will be missed.

If you think you have missed a dose speak to your doctor or other healthcare provider.

If you have any further questions ask your doctor or other healthcare provider.

4. Possible side effects

FLUCONAZOLE FRESENIUS can have side effects.

Not all side effects reported for FLUCONAZOLE FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving FLUCONAZOLE FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving FLUCONAZOLE FRESENIUS and tell your doctor immediately:

- A sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure.
- Swelling of the face, lips, tongue and windpipe with wheezing and difficulty in breathing.
- Severe, extensive, blistering skin rash, with peeling of skin.
- Seizures or fits (convulsions).

- Liver problems and toxicity causing abnormal weakness, loss of appetite, persistent nausea, vomiting and/or jaundice (where the skin, white of the eyes and inside of the mouth turn yellow).
- Decrease in the number of cells in the circulation that may lead to anaemia, increased susceptibility to infection, easy bruising or bleeding.
- Infection with symptoms of fever and a severe worsening of your general condition, or fever with local infection e.g. sore throat, pharynx (back of throat), mouth or urinary tract problems.
- Changes in heart rhythm.

These are all very serious side effects. If you have them, you may have had a serious reaction to FLUCONAZOLE FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.
- Skin rash.
- Feeling sick (nausea).
- Being sick (vomiting).
- Stomach ache or pain.
- Diarrhoea.
- Alterations in blood test results of liver function.

Less frequent side effects:

- Changes in how food tastes, dry mouth.
- Dizziness.
- Indigestion.
- Wind (flatulence).
- Loss of appetite.

- Itching or rash, wheals, swelling or blistering (hives).
- Increased sweating.
- Loss of appetite.
- Changes in blood test results of kidney function.
- Abnormal sleep (sleeplessness, drowsiness).
- Numbness, trembling.
- Pain in muscles.
- Feeling weak and tired.
- Fever.
- Increased levels of fats in the blood (cholesterol and triglycerides).
- Decreased levels of potassium leading to weakness and an irregular or fast heart beat.
- Hair loss (alopecia).

Side effects with an unknown frequency:

- Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FLUCONAZOLE FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-

kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store FLUCONAZOLE FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. Keep the product in the outer container until required for use.

Do not use FLUCONAZOLE FRESENIUS after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

The product must be used immediately after first opening the container.

Use only if the solution is clear and free from visible particles. Do not use if the bottle is damaged.

The bottles are for single use only. Once having been used, bottles and any remaining contents must be disposed of.

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. Contents of the pack and other information

What FLUCONAZOLE FRESENIUS contains

The active substance is fluconazole. 1 mL solution for infusion contains 2 mg of fluconazole.

One bottle with 50 mL FLUCONAZOLE FRESENIUS solution for infusion contains 100 mg of fluconazole.

One bottle with 100 mL FLUCONAZOLE FRESENIUS solution for infusion contains 200 mg of fluconazole.

One bottle with 200 mL FLUCONAZOLE FRESENIUS solution for infusion contains 400 mg of fluconazole.

The other ingredients are sodium chloride, water for injection, hydrochloric acid or sodium hydroxide (for pH-adjustment).

Sugar free.

What FLUCONAZOLE FRESENIUS looks like and contents of the pack

A clear to almost colourless sterile solution in clear transparent bottlepack polyethylene (KabiPac) containers packed in 50 mL; 100 mL and 200 mL bottles.

50 mL solution filled in 100 mL clear transparent polyethylene bottlepack container with cap and bromobutyl rubber disc with a hanger at the bottom.

100 mL solution filled in 100 mL clear transparent polyethylene bottlepack container with cap and bromobutyl rubber disc with a hanger at the bottom.

200 mL solution filled in 250 mL clear transparent polyethylene bottlepack container with cap and bromobutyl rubber disc with a hanger at the bottom.

Pack sizes of 1, 10; 20; 25; 30; 40 or 60 bottles.

Not all listed container sizes and pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.