

FINAL APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM

DIFLUCAN® IV INFUSION 100 ml

Fluconazole

Read all of this leaflet carefully before you are given DIFLUCAN IV Infusion.

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

If you have further questions, please ask your doctor or your pharmacist.

DIFLUCAN IV Infusion has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT DIFLUCAN IV Infusion CONTAINS

The active ingredient is fluconazole.

Each DIFLUCAN IV Infusion 100 ml contains 200 mg fluconazole (2 mg/ml).

The other ingredients in DIFLUCAN IV Infusion are sodium chloride and water for injection.

WHAT DIFLUCAN IV Infusion IS USED FOR

DIFLUCAN IV Infusion is one of a group of medicines called “antifungals”. The active ingredient is fluconazole.

DIFLUCAN IV Infusion is used to treat infections caused by fungi including yeasts and may also be used to stop you from getting a fungal infection.

BEFORE YOU ARE GIVEN DIFLUCAN IV Infusion

You should not be given DIFLUCAN IV Infusion if you

- have ever had an allergic reaction to:
 - any of the ingredients of DIFLUCAN IV Infusion
 - other medicines you have taken to treat a fungal infection.

The symptoms of an allergic reaction may include itching, reddening of the skin or difficulty in breathing.

- are taking astemizole (an antihistamine for allergies)
- are taking cisapride (used for stomach upsets)
- are taking erythromycin (for treating infections (antibiotic))
- are taking pimozide (for treating schizophrenia)
- are taking quinidine (used for irregular heartbeats)
- are pregnant or breastfeeding

Special care to be taken with DIFLUCAN IV Infusion

Tell your doctor if:

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

Pregnancy and Breastfeeding

You should not be given DIFLUCAN IV Infusion while you are pregnant or if you are breastfeeding.

If you are pregnant or breastfeeding, ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

Treatment with DIFLUCAN IV Infusion may lead to dizziness or seizures to occur and could affect your ability to drive or use machinery.

Important information about some of the ingredients

DIFLUCAN IV Infusion contains 15 mmol sodium per 100 ml dose. This should be taken into consideration by patients on a sodium restricted diet.

Taking other medicines with DIFLUCAN IV Infusion

Always tell your healthcare professional if you are taking any other medicine.

(This includes complimentary and traditional medicines).

Tell your doctor, immediately if you are taking astemizole (an antihistamine for treating allergies) or cisapride (used for stomach upsets) as these should not be taken with DIFLUCAN IV Infusion.

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

- warfarin (or similar drugs) that thin the blood to prevent blood clots
- calcium channel blockers or losartan for lowering blood pressure
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- vitamin A (as a trans-retinoid acid used to treat acne)
- water tablets, such as hydrochlorothiazide, used to treat fluid retention and high blood pressure
- atorvastatin, simvastatin or fluvastatin (for lowering cholesterol)
- midazolam used to help you sleep or for anxiety
- carbamazepine or phenytoin (used to control epilepsy)
- medicines for treating infections (antibiotics) such as azithromycin, rifampicin or rifabutin

- halofantrine (to treat malaria)
- ciclosporin, sirolimus or tacrolimus (to prevent transplant rejection)
- theophylline (used to control asthma)
- alfentanil, fentanyl or methadone (for treating pain)
- non-steroidal anti-inflammatory drugs (such as aspirin and ibuprofen) that are used to treat pain and fever
- celecoxib (used to treat some types of arthritis)
- amitriptyline, nortriptyline (used to treat depression)
- cyclophosphamide, prednisone or vinca alkaloids (for treating some forms of blood cancer e.g. leukaemia)
- saquinavir or zidovudine, also known as AZT (used in HIV-infected patients)
- oral contraceptives (the pill) (to prevent pregnancy)

HOW DIFLUCAN IV Infusion IS USED

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

DIFLUCAN IV Infusion will be given by your doctor or nurse as a slow injection (infusion) into your vein over approximately 30 minutes.

Elderly

The usual adult dose should be given unless you have kidney problems.

Patients with kidney problems

Your doctor may modify your dose, depending on your kidney function.

If you receive more DIFLUCAN IV Infusion than you should

If you are concerned that you may have been given too much DIFLUCAN IV Infusion, tell your doctor or nurse immediately. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucinations and paranoid behavior).

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you miss a dose of DIFLUCAN IV Infusion

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

POSSIBLE SIDE EFFECTS

DIFLUCAN IV Infusion can cause side effects.

Not all side effects reported for DIFLUCAN IV Infusion are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DIFLUCAN IV Infusion, please consult your doctor, pharmacist or other healthcare professional for advice.

You may develop allergic reactions. If you get any of the following symptoms, tell your doctor immediately.

- Sudden wheezing, difficulty in breathing or tightness in 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).

If you are an AIDS patient you are more likely to get severe skin reactions to medicines including DIFLUCAN IV Infusion.

Frequent side effects

- feeling sick (nausea)
- stomach discomfort
- diarrhoea
- wind
- rash
- headache

The side effects may cause discomfort or may be long lasting, check with your doctor or pharmacist.

Less frequent side effects

- itching
- seizures
- lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- high blood levels of cholesterol, fats or salt
- liver damage and yellowing of the skin and eyes (jaundice)
- hair loss
- dizziness
- altered sense of taste
- change in heart rate or rhythm
- insomnia (difficulty in sleeping)
- somnolence (feeling sleepy)
- myalgia (muscle pain)
- fatigue

- vertigo

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.

STORING AND DISPOSING OF DIFLUCAN IV Infusion

Store all medicines out of reach of children.

DIFLUCAN IV Infusion: Store at or below 30 °C. Do not freeze. Once open discard any unused infusion.

Do not use DIFLUCAN IV Infusion after the expiry date which is stated on the pack. The expiry date refers to the last day of the month.

PRESENTATION OF DIFLUCAN IV Infusion

DIFLUCAN IV Infusion 100 ml comes in a clear glass vial and contains 100 ml.

IDENTIFICATION OF DIFLUCAN IV Infusion

DIFLUCAN IV Infusion 100 ml is a clear colourless solution.

REGISTRATION NUMBER

DIFLUCAN IV Infusion 100 ml: Z/20.2.2/272

NAME AND ADDRESS OF REGISTRATION HOLDER

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DATE OF PUBLICATION

23 March 2015