PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DIFLUCAN® IV INFUSION 100 mL

Fluconazole

Sugar free

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, pharmacist, nurse or other health care provider.
- 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 is in this leaflet

1. What DIFLUCAN IV Infusion is and what it is used for
2. What you need to know before you use DIFLUCAN IV Infusion
3. How DIFLUCAN IV Infusion is used
4. Possible side effects
5. How to store DIFLUCAN IV Infusion
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1. What DIFLUCAN IV Infusion is and what it 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.

2. What you need to know before you use DIFLUCAN IV Infusion

DIFLUCAN IV Infusion should not be administered to you

- if you are hypersensitive (allergic) to fluconazole, other medicines you have taken to treat a fungal infection or any of the other ingredients of DIFLUCAN IV Infusion (listed in section 6). The symptoms of an allergic reaction may include itching, reddening of the skin or difficulty in breathing.
- if you are taking astemizole or terfenadine (an antihistamine for allergies)
- if you are taking cisapride (used for stomach upsets)
- if you are taking erythromycin (for treating infections (antibiotic))
- if you are taking pimozide (for treating schizophrenia)
- if you are taking quinidine (used for irregular heartbeats)
- if you are pregnant or breastfeeding

Warnings and precautions

Tell your doctor or health care provider before being given the infusion:

- if you have liver or kidney problems
- if you suffer from heart disease, including heart rhythm problems
- if laboratory investigations have shown abnormal levels of potassium, calcium or magnesium in your blood
- if you develop severe skin reactions (itching, reddening of the skin or difficulty in breathing)
- if you 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)
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking DIFLUCAN

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

Talk to your health care provider if the fungal infection does not improve, as alternative antifungal therapy may be needed.

Other medicines and DIFLUCAN IV Infusion

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

Tell your doctor immediately if you are taking astemizole or terfenadine (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 as a dose adjustment or monitoring may be required to check that the medicines are still having the desired effect:

- halofantrine (to treat malaria)
- amiodarone (used for treating uneven heartbeats 'arrhythmias')
- water tablets, such as hydrochlorothiazide, used to treat fluid retention and high blood pressure
- medicines for treating infections (antibiotics) such as azithromycin, rifampicin or rifabutin
- abrocitinib (used to treat atopic dermatitis, also known as atopic eczema)
- alfentanil, fentanyl or methadone (for treating pain)
- amitriptyline, nortriptyline (used to treat depression)
- amphotericin B, voriconazole (used to treat serious fungal infections)
- warfarin (or similar medicines) that thin the blood to prevent blood clots,

- benzodiazepines such as midazolam, triazolam used to help you sleep or for anxiety
- carbamazepine or phenytoin (used to control epilepsy)
- calcium channel blockers or losartan for lowering blood pressure
- celecoxib (used to treat some types of arthritis)
- ciclosporin, sirolimus or tacrolimus (to prevent transplant rejection)
- cyclophosphamide, prednisone, vinca alkaloids or ibrutinib (for treating some forms of blood cancer e.g. leukaemia)
- atorvastatin, simvastatin or fluvastatin (for lowering cholesterol)
- ivacaftor, alone or combined with other medicines (used for treating cystic fibrosis)
- lurasidone (used to treat schizophrenia)
- non-steroidal anti-inflammatory drugs (such as aspirin and ibuprofen) that are used to treat pain and fever
- olaparib (used for treating ovarian cancer)
- oral contraceptives (the pill) (to prevent pregnancy)
- saquinavir or zidovudine, also known as AZT (used in HIV-infected patients)
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide
- theophylline (used to control asthma)
- tofacitinib (used for treating rheumatoid arthritis)
- tolvaptan (used to treat low levels of sodium in blood or to slow kidney function decline)
- vitamin A (as a trans-retinoid acid used to treat acne)

Pregnancy and breastfeeding

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 health care provider for advice before taking this medicine.

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

Effective contraceptive measures must be used in women of childbearing potential throughout treatment with DIFLUCAN and for approximately 1 week after the final dose.

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.

It is not always possible to predict to what extent DIFLUCAN IV Infusion 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 DIFLUCAN IV Infusion affects them.

DIFLUCAN IV Infusion contains sodium

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

3. 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.

Your doctor will tell you how long your treatment with DIFLUCAN IV Infusion will last. If you have the impression that the effect of DIFLUCAN IV Infusion is too strong or too weak, tell your doctor or pharmacist.

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 behaviour).

Since a health care provider will administer DIFLUCAN IV Infusion, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you miss a dose of DIFLUCAN IV Infusion

Since a health care provider will administer DIFLUCAN IV Infusion, it is unlikely that the dose will be missed. However, tell your doctor or nurse if you think that a dose has been forgotten.

4. 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 health care provider for advice.

You may develop allergic reactions. If any of the following happens, 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).
- Hypersensitivity reaction with skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine); stop receiving DIFLUCAN and seek medical attention immediately if you notice any of the following symptoms: widespread rash, high body temperature and enlarged lymph nodes (swollen glands) (DRESS syndrome or drug hypersensitivity syndrome)

These are all serious side effects. You may need urgent medical attention.

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

Tell your doctor if you notice any of the following:

Frequent side effects

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

Less frequent side effects

- insomnia (difficulty in sleeping)
- somnolence (feeling sleepy)
- seizures (fits)

- dizziness
- tingling or pricking (pins and needles)
- altered sense of taste
- sensation of spinning (vertigo)
- indigestion
- wind
- dry mouth
- decrease in bile flow
- yellowing of the skin and eyes (jaundice)
- higher than normal levels of bilirubin in your blood (seen in blood tests)
- itching
- increased sweating
- myalgia (muscle pain)
- fatigue
- tiredness
- general feeling of being unwell
- fever
- 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
- low blood potassium levels
- tremor
- change in heart rate or rhythm
- liver damage or failure
- hair loss

If any of the side effects gets serious, or 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 or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DIFLUCAN IV Infusion.

5. How to store DIFLUCAN IV Infusion

- Store all medicines out of reach of children.
- 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.

6. Contents of the pack and other information

What DIFLUCAN IV Infusion contains

- The active substance is fluconazole. Each DIFLUCAN IV Infusion 100 mL vial contains 200 mg fluconazole (2 mg/mL).
- The other ingredients are sodium chloride and water for injection.

What DIFLUCAN IV Infusion looks like and contents of the pack

DIFLUCAN IV Infusion 100 mL is a clear colourless solution.

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

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

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