PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DIFLUCAN® 50 mg/5 mL Powder for oral suspension

DIFLUCAN® 200 mg/5 mL Powder for oral suspension

Fluconazole

Contains sugar

Each 5 mL of DIFLUCAN 50 mg/5 mL suspension contains 2,88 g sucrose.

Each 5 mL of DIFLUCAN 200 mg/5 mL suspension contains 2,73 g sucrose.

Read all of this leaflet carefully before you start taking DIFLUCAN

- 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 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 is and what it is used for
2. What you need to know before you take DIFLUCAN
3. How to take DIFLUCAN
4. Possible side effects
5. How to store DIFLUCAN
6. Contents of the pack and other information

1. What DIFLUCAN is and what it is used for

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

DIFLUCAN 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 take DIFLUCAN

Do not take DIFLUCAN

- if you are hypersensitive (allergic) to fluconazole, other medicines you have taken to treat a fungal infection, or to any of the other ingredients of DIFLUCAN (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

Take special care with DIFLUCAN:

- 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 taking 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

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.

There are some medicines that may interact with DIFLUCAN. 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 take DIFLUCAN while you are pregnant or if you are breastfeeding.

Effective contraceptive measures must be considered 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 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 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 affects them.

DIFLUCAN suspension contains sucrose (sugar)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This should be taken into account if you have diabetes. DIFLUCAN Suspension may be harmful to your teeth if used for prolonged periods (2 weeks or more).

DIFLUCAN suspension contains sodium benzoate (as preservative)

Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take DIFLUCAN

Do not share medicines prescribed for you with any other person.

Always take DIFLUCAN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You can take DIFLUCAN Suspension with or without a meal at any time of the day.

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 are not sure, ask your doctor or pharmacist.

It is best to take your medicine at the same time each day. You may take it with or without meals.

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

If you take more DIFLUCAN than you should

Taking too much DIFLUCAN may make you unwell. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take DIFLUCAN

Do not take a double dose to make up for forgotten individual doses. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

4. Possible side effects

DIFLUCAN can have side effects.

Not all side effects reported for DIFLUCAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DIFLUCAN, 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 taking 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.

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.

5. How to store DIFLUCAN

- Store all medicines out of reach of children.
- Store suspension between 5 °C and 30 °C once reconstituted. Do not freeze. Discard unused portion after 2 weeks.
- Do not use DIFLUCAN after the expiry date which is stated on the pack. The expiry date refers to the last day of the month.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DIFLUCAN contains

The active substance is fluconazole.

DIFLUCAN 50 mg/5 mL Powder for oral suspension contains 50 mg fluconazole per 5 mL and DIFLUCAN 200 mg/5 mL Powder for oral suspension contains 200 mg fluconazole per 5 mL.

The other ingredients in DIFLUCAN Powder for oral suspension are sucrose, colloidal anhydrous silica, titanium dioxide, xanthan gum, sodium citrate dihydrate, citric acid anhydrous, sodium benzoate and natural orange flavour as flavourant.

What DIFLUCAN looks like and contents of the pack

DIFLUCAN 50 mg/5 mL and 200 mg/5 mL Powder for oral suspension is a dry white to off-white powder. Your pharmacist will add 24 mL of water to the powder to produce an off-white orange flavoured suspension. In each bottle the mixture of powder and water makes 35 mL of suspension.

DIFLUCAN 50 mg/5 mL and 200 mg/5 mL comes in a plastic bottle with a child – resistant cap containing 35

mL of reconstituted suspension.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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