PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

Fluzol® 50 (capsules)

Fluzol® 200 (capsules)

Fluconazole

Each FLUZOL 50 capsule contains sugar (lactose monohydrate 48,75 mg).

Each FLUZOL 200 capsule contains sugar (lactose monohydrate 195,0 mg).

Read all of this leaflet carefully before you start taking FLUZOL

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FLUZOL 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 FLUZOL is and what it is used for

2. What you need to know before you take FLUZOL

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1. What FLUZOL is and what it is used for

FLUZOL contains fluconazole which is an antifungal agent used to treat serious fungus infections that may occur in different parts of the body.

Your doctor has prescribed FLUZOL for you to treat the specific fungal infection you have. FLUZOL can be prescribed alone or in combination with other medicines.

2. What you need to know before you take FLUZOL

Do not take FLUZOL if:

- You are hypersensitive (allergic) to fluconazole, to other medicines you have taken to treat fungal infections or any of the other ingredients of FLUZOL (listed in section 6).
- You are taking antihistamines called terfenadine or astemizole.
- You are taking a medicine called cisapride to increase your bowel movements.
- You are taking pimozide used for treating mental illness.
- You are taking quinidine used for treating heart arrhythmia.
- You are taking erythromycin an antibiotic for treating infections.
- You are pregnant or breastfeeding.
- You should not take multiple doses if you have a serious kidney problem.

Warnings and precautions:

Take special care with FLUZOL:

Before taking this medication, tell your doctor if:

- You have kidney problems.
- You suffer from liver problems or start developing liver problems while taking this medicine. If you develop the following symptoms, you should speak to your doctor, as they may be signs of serious liver problems: feeling tired all the time, loss of appetite and weight loss (anorexia), feeling nauseous all the time, vomiting and jaundice (yellowing of the white of the eyes and skin).

- You are HIV positive.
- You have been diagnosed with any malignancies (cancer).
- You suffer from heart disease, including heart rhythm problems.
- You have abnormal levels of potassium in your blood (seen in blood tests).
- You develop severe skin reactions (itching, reddening of the skin or difficulty breathing).
- You develop signs of 'adrenal insufficiency' where the adrenal glands do not produce adequate amounts of certain steroid hormones such as cortisol, which may present with the following symptoms: 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 of the skin, swelling, dry skin, abnormal odour, flaking and/or mouth sores after taking FLUZOL.

Serious skin reactions including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have been reported in association with fluconazole treatment. Stop taking FLUZOL 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 FLUZOL:

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

Please advise your doctor or health care provider if you are using any of the following products as these should not be taken with FLUZOL (see section "Do not take FLUZOL if"):

- Cisapride a medicine used to increase bowel movements.
- Terfenadine and astemizole, antihistamines for treating allergies.
- Pimozide, used for treating mental illness.
- Quinidine, used for treating heart arrhythmia.

- Erythromycin, an antibiotic for treating infections.

The use of the following medicine together with FLUZOL cannot be recommended and should be avoided:

- Halofantrine (used for treating malaria).

The use of the following medicine together with FLUZOL should be used with caution:

- Amiodarone (used for treating uneven heartbeats ‘arrhythmias’).

FLUZOL may interact with the following medicines. Make sure your doctor knows if you are taking any of these medicines as a dose adjustment or monitoring may be required to check that the medicines are still having the desired effect:

- Blood thinning agents to prevent blood clots e.g. warfarin or similar medicines.
- Medicines against epilepsy e.g. phenytoin, carbamazepine.
- Oral antidiabetic medicines such as chlorpropamide, glibenclamide, glipizide or tolbutamide.
- Theophylline, a medicine used to control asthma.
- Antiretroviral medicines e.g. zidovudine, saquinavir, nevirapine.
- Ciclosporin, everolimus, sirolimus and tacrolimus, immunosuppressants used after organ transplants to prevent rejection.
- Anti-anxiety medicines called benzodiazepines (e.g. midazolam, triazolam).
- Anti-TB medicine called rifabutin (FLUZOL may also interact with the anti-TB medicine rifampicin by decreasing the blood level of this medicine which could lead to ineffectiveness of this medicine).
- The diuretic (medicine that increases urination), hydrochlorothiazide increases the blood levels of FLUZOL.
- Abrocitinib (used to treat atopic dermatitis, also known as atopic eczema).
- Alfentanil, fentanyl (used as anaesthetic).

- Amitriptyline, nortriptyline (used as anti-depressant).
- Amphotericin B, voriconazole (anti-fungals).
- Calcium channel blockers e.g. Nifedipine, isradipine, amlodipine, verapamil, felodipine and the angiotensin II-receptor blocker losartan (high blood pressure medication).
- Celecoxib, flurbiprofen, naproxen, ibuprofen, lornoxicam, meloxicam, diclofenac (Non-Steroidal Anti-Inflammatory Drugs (NSAID)).
- Cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar medicines) used for treating cancer.
- Statins (atorvastatin, simvastatin and fluvastatin or similar medicines) used for reducing high blood cholesterol levels.
- Ibrutinib (used for treating blood cancer).
- Ivacaftor (used for treating cystic fibrosis).
- Olaparib (used for treating ovarian cancer).
- Lurasidone (used to treat schizophrenia).
- Methadone (used for pain).
- Prednisone (steroid).
- Tofacitinib (used for treating rheumatoid arthritis).
- Tolvaptan used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline.
- Vitamin A (nutritional supplement).
- Oral contraceptives.

FLUZOL with food or drink:

You can take this capsule before or after meals, the presence of food will not influence the absorption of the medicine. Do not chew, crack or open the capsule and swallow it whole.

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.

FLUZOL should not be used during pregnancy or by women who plan to become pregnant.

An effective form of birth control should be used during treatment with this product. Check with your doctor immediately if you think you have become pregnant while taking this medicine.

FLUZOL should not be used during breastfeeding.

Driving and using machines:

FLUZOL should not affect your ability to drive or use machinery, but you should refrain from driving or using machinery until you know how this medicine affects you as it may cause nausea, dizziness, headache or seizures (fits).

FLUZOL contains lactose:

FLUZOL contains lactose monohydrate. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take FLUZOL.

FLUZOL contain lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take FLUZOL

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

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

If you have the impression that the effect of FLUZOL is too strong or too weak, talk to your doctor or pharmacist.

Follow your doctor's advice. The capsules should be swallowed whole with a glass of water and should be taken the same time each day.

Cryptococcal meningitis:

***Adults*:** Initial dose is 400 mg on the first day; followed by 200 mg to 400 mg daily. Duration of therapy is usually 8 weeks.

Maintenance therapy to prevent reoccurrence of cryptococcal meningitis in patients with AIDS:

***Adults*:** 100 mg to 200 mg per day.

Candidiasis (thrush):

Adults: Starting dose may differ from 50 mg to 400 daily depending on the type of candidiasis.

Prevention of fungal infections in patients who receive chemotherapy and/or radiation therapy:

Adults: 50 mg to 400 mg daily depending on the patients risk for developing fungal infections.

Fungal infections of the skin or nails:

Adults: 150 mg administered as a single dose once a week.

If your kidney function is impaired your doctor may reduce your dosage.

If you take more FLUZOL than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining capsules with you, so that the doctor knows what the person has taken.

If you forget to take FLUZOL:

Take the missed dose as soon as possible. However, if it is almost time for you next dose, continue to take the next capsule at the usual time. Do not take a double dose.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you stop taking FLUZOL:

It is important to keep taking your medicine for as long as your doctor prescribes them. Do not stop taking your medicine without consulting your doctor first.

4. Possible side effects

FLUZOL can have side effects.

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

If any of the following happens, stop taking FLUZOL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden wheezing, difficulty in breathing or tightness in the chest skin rash, hives or itching skin, reddening of the skin
- Fever and chills
- Swelling of face, eyelids or lips, arms, hands, lower legs or feet

- Difficulty in swallowing
- Severe skin reactions that causes blistering, peeling or loosening of skin (this can affect the mouth and tongue)
- Hypersensitivity reaction with widespread skin rash, fever, swollen glands, enlarged lymph nodes, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)) or drug hypersensitivity syndrome.
- FLUZOL may affect your liver leading to liver damage and failure. The signs of liver problems include:
    - tiredness
    - loss of appetite
    - vomiting
    - yellowing of the skin or the whites of the eyes (jaundice)

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea
- Headache
- Vomiting
- Stomach pain
- Diarrhoea
- Flatulence (wind)
- Increases in blood tests of liver function
- Rash

Less frequent side effects:

- Reduction in red blood cells which can make skin pale and cause weakness or breathlessness
- Lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- Red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes
- Decreased appetite
- Low blood potassium
- Blood chemistry changes (high blood levels of cholesterol, fats)
- Dizziness
- Fits
- Sensation of tingling, pricking or numbness
- Unusual or unpleasant taste in mouth, with changes in sense of taste
- Shaking
- Nervousness
- Restlessness
- Sleeping problems
- Feeling drowsy
- Blurred vision
- Sensation of your head spinning (vertigo)
- Abnormal electrocardiogram (ECG) (the ability of your heart to conduct electricity)
- Change in heart rate or rhythm
- Constipation
- Difficult digestion
- Dry mouth

- Thirst
- Temporary hair loss
- Increased sweating
- Muscle pain and overactivity
- Excessive passing of urine
- Female sexual dysfunction, bleeding between menstrual cycles, excessive menstrual bleeding, vaginal discharge
- Unusual tiredness or weakness
- General feeling of being unwell
- Fever

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 (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FLUZOL.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration (HCR) via: https://pvi1j.solutions.iqvia.com or patient.safety.sac@sandoz.com.

5. How to store FLUZOL

Store at or below 25 ºC.

Protect from light.

Do not remove the blisters from the outer container until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the capsules after the expiry date printed on the carton or label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FLUZOL contains:

Each FLUZOL 50 capsule contains 50 mg fluconazole.

Each FLUZOL 200 capsule contains 200 mg fluconazole.

Inactive ingredients of FLUZOL:

Anhydrous colloidal silica, hard gelatin capsule**, lactose monohydrate, magnesium stearate, maize starch, sodium lauryl sulfate.

***Hard Gelatin capsule** composed of:* Black iron oxide (E 172), gelatin, indigo carmine FD&C Blue 2, *Ponceau 4 R, propylene glycol (E 1520), shellac, titanium dioxide.

Ponceau 4 R is only available in FLUZOL 200 hard gelatin capsules.

What FLUZOL looks like and contents of the pack:

FLUZOL 50: Hard gelatin capsules, snap-fit closure, turquoise cap / white body with the imprint FC50, containing a white odourless powder.

FLUZOL 200: Hard gelatin capsules, snap-fit closure, purple cap / white body, with imprint FC200, containing a white odourless powder.

FLUZOL 50: White, opaque PVC/Aluminium blisters strips containing 14 capsules.

FLUZOL 200: White, opaque PVC/Aluminium blisters strips containing 28 or 30 capsules.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

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FLUZOL 50: 36/20.2.2/0261

FLUZOL 200: 36/20.2.2/0263

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07