PATIENT INFORMATION LEAFLET

FINGOSOL 0.5

SCHEDULING STATUS

S4

FINGOSOL 0.5 (0,5 mg capsules)

Fingolimod Hydrochloride

Sugar free

Read all of this leaflet carefully before you start taking FINGOSOL 0.5

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- FINGOSOL 0.5 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 FINGOSOL 0.5 is and what it is used for

The active substance of FINGOSOL 0.5 is fingolimod and it is used to treat relapsing-remitting multiple sclerosis (MS), more specifically in:

- Patients who have failed to respond despite treatment with an MS treatment.

- Patients who have rapidly evolving severe MS.

FINGOSOL 0.5 does not cure MS, but it helps to reduce the number of relapses and to slow down the progression of physical disabilities due to MS.

2. What you need to know before you are administered FINGOSOL 0.5

Do not take FINGOSOL 0.5

- If you are allergic to fingolimod or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant and/or breastfeeding

- If, in the last 6 months, you have had a heart attack, angina, stroke or warning of a stroke or certain types of heart failure.
- If you have a lowered immune response (due to an immunodeficiency syndrome, a disease or to medicines that suppress the immune system).
- If you have a severe active infection or active chronic infection such as hepatitis or tuberculosis.
- If you have an active cancer.
- if you have certain types of irregular or abnormal heartbeat (arrhythmia), including patients in whom the electrocardiogram (ECG) shows prolonged QT interval before starting FINGOSOL 0.5.
- If you are taking or have recently taken medicine for irregular heartbeat such as quinidine, disopyramide, amiodarone or sotalol.

Warnings and precautions

At the beginning of treatment, FINGOSOL 0.5 can cause the heart rate to slow down. FINGOSOL 0.5 can also cause an irregular heartbeat, especially after the first dose. Irregular heartbeat usually returns to normal within one day. Slow heart rate usually returns to normal within one month. If your heart rate slows down after your first dose, you may feel dizzy or tired, or may become aware of your heartbeat.

You will be observed hourly by a health care professional for at least 6 hours after taking the first dose of FINGOSOL 0.5 so that your heart rate and blood pressure can be checked. You will be required to have an ECG

(electrocardiogram) to check the health of your heart before you start FINGOSOL 0.5 and a second ECG at the end of the 6-hour observation. In case of an abnormal ECG recording or slow heart rate at the end of the 6-hour observation period, you may be observed overnight by a health care professional.

Tell your doctor or health care provider before taking/being given FINGOSOL 0.5**:**

- If you have severe breathing problems during sleep (severe sleep apnoea).
- If you have been told you have an abnormal electrocardiogram.
- if you suffer from symptoms of slow heart rate (e.g. dizziness, nausea, or palpitations).
- If you are taking or have recently taken medicines that slow your heart rate (such as beta blockers, verapamil, diltiazem or ivabradine, digoxin, anticholinesteratic agents or pilocarpine).
- If you have a history of sudden loss of consciousness or fainting (syncope).
- If you plan to get vaccinated.
- If you have never had chickenpox.
- If you have or have had visual disturbances or other signs of swelling in the central vision area (macula) at the back of the eye (a condition known as macular oedema, see below), inflammation or infection of the eye (uveitis), or if you have diabetes (which can cause eye problems).
- If you have an existing infection or symptoms indicating an infection.
- If you have severe liver problems.
- If you have high blood pressure that cannot be controlled by medicines.

- If you have severe lung problems or smoker’s cough.

If any of these applies to you, tell your doctor or nurse before you are given FINGOSOL 0.5.

Children and adolescents

Do not give FINGOSOL 0.5 to children under the age of 18 as safety and efficacy has not been established.

Other medicines and FINGOSOL 0.5

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

It is particularly important that you mention the following medications:

- St John's wort used in the treatment of mild to moderate depression.
- Natalizumab used to treat multiple sclerosis and Crohn's disease.
- Teriflunomide used to treat relapsing forms of multiple sclerosis.
- Mitoxantrone used in the treatment of cancer.
- Verapamil, atenolol and diltiazem used in the treatment of high blood pressure and chest pain.
- Ivabradine and digoxin used for chest pain and heart failure.
- Pilocarpine used to treat pressure inside the eye.
- Antibiotics to treat infections such as ketoconazole, clarithromycin or telithromycin.

Pregnancy and breastfeeding

FINGOSOL 0.5 should not be used in pregnancy and during breastfeeding as safety has not been established.

Driving and using machines

FINGOSOL 0.5 has little to no influence on the ability to drive. However, drowsiness may occur when starting treatment. It is recommended that a period of 6 hours is observed after starting treatment before driving and using machines.

3. How to take FINGOSOL 0.5

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

Always use FINGOSOL 0.5 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with FINGOSOL 0.5 will last.

The usual dose is one 0,5 mg capsule taken orally once daily.

If you take more FINGOSOL 0.5 than you should

Do not exceed the recommended dosage. 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 FINGOSOL 0.5

Do not take a double dose to make up for forgotten individual doses.

If a dose is missed, treatment should be continued with the next dose as planned.

4. Possible side effects

FINGOSOL 0.5 can have side effects.

Not all side effects reported for FINGOSOL 0.5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FINGOSOL 0.5, please consult your health care provider for advice.

If any of the following happens, stop taking / using FINGOSOL 0.5 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting

These are all very serious side effects. If you have them, you may have had a serious reaction

to FINGOSOL 0.5. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you

notice any of the following:

- Coughing with phlegm, chest discomfort, fever (signs of lung disorders).
- Herpes virus infection (shingles or herpes zoster) with symptoms such as blisters, burning, itching or pain of the skin, typically on the upper body or the face. Other symptoms may be fever and weakness in the early stages of infection, followed by numbness, itching or red patches with severe pain.
- Slow heartbeat (bradycardia), irregular heart rhythm.
- A type of skin cancer called basal cell carcinoma (BCC) which often appears as a pearly nodule, although it can also take other form.

These are all serious side effects.

You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Severe headache often accompanied by nausea, vomiting and sensitivity to light (migraine)
- Dizziness
- Depression
- Disturbances in eyesight and pain in the eye

- Hypertension (high blood pressure)
- Diarrhoea
- Itchy, red, burning rash (eczema)
- Hair loss
- Itchiness
- Back pain
- Lack of energy
- Ringworm, a fungal infection of the skin (tinea versicolor)
- Blood fat (triglycerides) level increased
- Breathlessness.

Less Frequent side effects:

- Cancer of the lymphatic system (lymphoma)
- Cancer of the skin (melanoma, Kaposi sarcoma and squamous cell carcinoma)
- Low level of certain white blood cells (neutrophils) which could lead to infections
- Low level of platelet count (thrombocytopenia) which increases risk of bleeding or bruising
- Depressed mood
- A condition called posterior reversible encephalopathy syndrome (PRES). Symptoms may include sudden onset of severe headache, confusion, seizures and/or vision disturbances

- Swelling of the eye (swelling in the central vision area of the retina at the back of the eye) with symptoms such as shadows or blind spot in the centre of the vision, blurred vision, problems seeing colours or details
- Nausea

Side effects of which is frequency is unknown:

- Swelling or puffiness of the tissue under your skin, especially in your legs or arms.
- Risk of a rare brain infection called progressive multifocal leukoencephalopathy (PML). Symptoms might also arise that you might not become aware of by yourself, such as changes in mood or behaviour, memory lapses, speech and communication difficulties, which your doctor may need to investigate further to rule out PML.
- Allergic reactions, including symptoms of rash or itchy hives, swelling of lips, tongue or face, which are more likely to occur on the day you start with treatment.

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 nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction 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 FINGOSOL 0.5.

5. How to store FINGOSOL 0.5

Store all medicines out of reach of children.

Protect from light / moisture.

Do not use after the expiry date stated on the label / carton / vial.

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 FINGOSOL 0.5 contains

The active substance is: Fingolimod Hydrochloride

The other ingredients are:

- Low-substituted hydroxypropyl cellulose
- Magnesium stearate
- Microcrystalline cellulose
- Iron oxide yellow
- Titanium dioxide
- Black iron oxide
- Propylene glycol

- Shellac.

What FINGOSOL 0.5 looks like and contents of the pack

FINGOSOL 0.5 is a hard gelatin capsule with a white opaque body and yellow opaque cap imprinted with “WF5” containing white to off-white powder.

The capsules are contained within silver aluminium/aluminium blister strips or silver aluminium/clear transparent PVDC/PVC blister strips containing 7, 10 or 14 capsules per blister strip.

Holder of Certificate of Registration

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Not applicable.

Registration number

To be allocated.