FINAL APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

MODLIFIN 0,5 mg (Capsules)

Fingolimod

Sugar free

Read all of this leaflet carefully before you start taking MODLIFIN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MODLIFIN** 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 MODLIFIN is and what it is used for

- **MODLIFIN** contains the active substance fingolimod. Fingolimod helps to fight against cells that cause inflammation from reaching the brain. This reduces nerve damage caused by MS.
- **MODLIFIN** is used to treat relapsing (returning) multiple sclerosis (MS).

- **MODLIFIN** does not cure MS, but it helps to reduce the number of (relapses) returns that occur and to slow the build-up of physical problems due to MS (disability progression).

2. What you need to know before you take MODLIFIN

Do not take MODLIFIN:

- if you are hypersensitive (allergic) to fingolimod or any of the other ingredients of **MODLIFIN** (listed in section 6)
- if you are pregnant or breastfeeding
- if you are taking medicines for irregular heartbeat such as quinidine, procainamide, amiodarone or sotalol
- 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 an irregular or abnormal heartbeat or your ECG shows a prolonged QT interval.
- If you are a woman of childbearing potential not using effective contraception.

Warnings and precautions

Special care should be taken with **MODLIFIN**:

- You will be observed hourly by a health care professional for at least 6 hours after taking the first dose of **MODLIFIN** 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 **MODLIFIN** and a second ECG at the end of the 6-hour observation. In case of 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.
- During treatment with **MODLIFIN** you may be more prone to infections because **MODLIFIN** lowers the white blood cell counts. If you already have an infection, your doctor may delay treatment with **MODLIFIN** until the infection resolves. During treatment with **MODLIFIN**, tell your doctor if you notice any signs of infection such as fever, headache, flu-like symptoms.

- If you think you have an infection, have fever, feel like you have the flu, have shingles or have a headache accompanied by stiff neck, sensitivity to light, nausea, rash, and/or confusion or seizures (fits) (these may be symptoms of meningitis and/or encephalitis caused by a fungal or herpes viral infection), contact your doctor straight away, because it could be serious and life-threatening.
- If you have never had chickenpox, your doctor will check your immunity against the virus that causes it (varicella zoster virus). If you are not protected against the virus, you may need a vaccination before you start treatment with **MODLIFIN**. If this is the case, your doctor will delay the start of treatment with **MODLIFIN** until one month after the full course of vaccination is completed.
- Human papilloma virus (HPV) infections can occur with **MODLIFIN** treatment. Your doctor will discuss taking the HPV vaccine with you. Regular PAP tests is recommended.
- If you have recently received a vaccination, its effectiveness may be reduced during treatment with **MODLIFIN** and for 2 months after stopping.
- 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, inflammation or infection of the eye (uveitis) or diabetes, your doctor may want you to undergo an eye examination. After 3-4 months of treatment your doctor may also ask you to go for an eye examination.
- At the beginning of treatment, **MODLIFIN** may cause your heart rate to slow down. As a result, you may feel dizzy or tired, or be consciously aware of your heartbeat, or your blood pressure may drop. If these effects are severe, tell your doctor, because you may need treatment right away. **MODLIFIN** can also cause an irregular heartbeat, especially after the first dose. Irregular heartbeat usually returns to normal in less than one day. Slow heart rate usually returns to normal within one month. During this period, no clinically significant heart rate effects are usually expected.
- If you have a history of slow heart rate or any other heart issues tell your doctor.
- You will have a blood test to check your liver function before you start taking **MODLIFIN**. **MODLIFIN** may affect your liver function. If you notice yellowing of your skin or the whites of your eyes, abnormally

dark urine or unexplained nausea, vomiting and tiredness during treatment, tell your doctor straight away.

- Your doctor may wish to switch you from another therapy to **MODLIFIN**. If so, a blood test will be done to ensure your previous treatment has not resulted in any abnormalities.
- **MODLIFIN** may have an adverse effect on your lungs. Tell your doctor if you have or previously has any respiratory issues.
- Talk to your doctor before stopping treatment with **MODLIFIN**. If you suddenly stop treatment your MS symptoms may return more aggressively.
- Tell your doctor if you notice any lesions, rash or growths on your skin. Wear protective clothing when you go out in the skin and apply sunscreen regularly.

Children and adolescents

MODLIFIN is not for use in children and adolescents.

Other medicines and MODLIFIN

- Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
- Please talk to your doctor or pharmacist if you are taking any of the following medicines:
    - Medicines for an irregular heartbeat such as quinidine, procainamide, amiodarone or sotalol.
    - Medicines that slow down heartbeat like beta-blockers (such as atenolol), calcium channel blockers (such as verapamil or diltiazem) or ivabradine or digoxin. Your doctor may decide not to use **MODLIFIN** or may refer you first to a cardiologist to change your medicines due to a possible added effect on slowing down heartbeat on the first days you start **MODLIFIN**.
    - Medicines that suppress or modulate the immune system including other medicines used to treat MS such as beta-interferon, glatiramer acetate, natalizumab, or mitoxantrone, dimethyl

fumarate, teriflunomide, alemtuzumab or corticosteroids due to a possible added effect on the immune system.

- Vaccines. If you need to receive a vaccine, seek your doctor's advice first. During and for up to 2 months after treatment with **MODLIFIN**, administration of some vaccines containing live virus (live attenuated vaccines) may result in infection that the vaccination should prevent, while others may not work well. Check with your doctor or pharmacist.

Pregnancy, breastfeeding and fertility

- You should not use this medicine during pregnancy or while you are 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 healthcare provider for advice before taking this medicine.
- If you are a woman of childbearing age, you should use effective contraception during treatment with **MODLIFIN** and for 2 months after stopping treatment.

Driving and using machines

- **MODLIFIN** may cause dizziness and blurred vision.
- It is not always possible to predict to what extent **MODLIFIN** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **MODLIFIN** affects you.

3. How to take MODLIFIN

- Do not share medicines prescribed for you with any other person.
- Always take **MODLIFIN** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The usual dose is one 0,5 mg capsule taken once a day.
- If you have the impression that the effect of **MODLIFIN** is too strong or too weak, tell your doctor or

pharmacist.

If you take more MODLIFIN than you should

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

If you forget to take MODLIFIN

If you forget to take **MODLIFIN**, wait and take your next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you have been on **MODLIFIN** therapy less than 2 weeks and you forget a dose, call your doctor immediately. Your doctor may decide to observe you at the time you take the next dose.

If you stop taking MODLIFIN

- Do not stop taking **MODLIFIN** or change your dose without talking to your doctor.
- **MODLIFIN** will stay in your body for up to 2 months after you stop taking it. Your white blood cell count (lymphocyte count) may also remain low during this time and the side effects described in this leaflet may still occur.
- If you have stopped **MODLIFIN** for at least 1 day during your first month of treatment or if you stopped **MODLIFIN** more than 2 weeks after you have been on **MODLIFIN** treatment for more than a month, the initial effect on your heart rate may occur again. When you restart your **MODLIFIN** therapy, your doctor may decide to observe you with heart rate and blood pressure measurements every hour, to run ECG's and he may decide to monitor you overnight.

4. Possible side effects

- **MODLIFIN** can have side effects.

FINAL APPROVED PATIENT INFORMATION LEAFLET

- Not all side effects reported for **MODLIFIN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MODLIFIN**, please consult your doctor, pharmacist or other healthcare professional for advice.
- If any of the following happens, stop taking **MODLIFIN** and tell your doctor immediately or go to the casualty department at your nearest hospital:
    - Difficulty breathing
    - Severe skin rash or itching
    - Swollen tongue or lips

These are all very serious side effects. If you have them, you may have had a serious reaction to **MODLIFIN**. 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:
    - Fever, flu-like symptoms accompanied by fatigue and muscle pain, headache accompanied by stiff neck, sensitivity to light, nausea, rash, and/or confusion or seizures (fits); these may be signs of a serious infection.
    - Worsening of multiple sclerosis symptoms.
    - Lesions on your skin.
    - Blurred vision or loss of vision.
    - Slowing of heart rate.
    - Pain in your abdomen, yellow skin accompanied by nausea and vomiting; this may indicate a problem with your liver.

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

- Tell your doctor if you notice any of the following:
    - <u>Frequent side effects</u>

- Sinusitis, cough
- Enlarged lymph nodes accompanied by fever, cough, runny nose.
- Depression
- Headache, dizziness, migraine
- High blood pressure
- Shortness of breath
- Diarrhoea
- Skin rash (eczema), itchy skin, hair loss
- Tiredness and lack of energy
- Loss of weight

- Less frequent side effects
  - Nodules or masses on skin, especially face, neck or head.
  - Swelling of arms or legs.
  - Chills, increased heart rate, weakness and fatigue.
  - Nausea

- 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. This includes any possible side effects not listed in this leaflet. 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 **MODLIFIN**.

FINAL APPROVED PATIENT INFORMATION LEAFLET

5. How to store MODLIFIN

- Store all medicines out of reach of children.
- Store below 25 °C.

6. Contents of the pack and other information

What MODLIFIN contains

- The active substance is fingolimod.
- Each capsule contains 0,5 mg fingolimod.
- The other ingredients are: starch and magnesium stearate
- The capsule cap is made up of gelatin, water, titanium dioxide (E171) and iron oxide yellow (E172). The capsule body is made up of gelatin, water and titanium dioxide (E171).

What MODLIFIN looks like and contents of the pack

- **MODLIFIN** capsules are bright yellow opaque/white opaque size “3” hard gelatin capsules imprinted with “FO 0,5 mg” on the cap and two radial bands on the capsule body with yellow ink containing white to off-white powder. Each capsule is approximately 15,8 mm in length.
- **MODLIFIN 0,5 mg** capsules are packed in Alu-PVC/PVdC blister packs comprising lidding foil made of plain aluminium foil and clear PVC/PVdC film as forming foil.
- Pack sizes: 10 & 30

HOLDER OF CERTIFICATE OF REGISTRATION

Accord Healthcare (Pty) Ltd

Building 2, Tuscany Office Park,

6 Coombe Place

Rivonia

Johannesburg

FINAL APPROVED PATIENT INFORMATION LEAFLET

South Africa

This leaflet was last revised in

18 April 2023

Registration number

56/34/0213