PATIENT INFORMATION LEAFLET FOR MYELENEA

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

MYELENEA capsules.

Read all of this leaflet carefully before you start taking MYELENEA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **MYELENEA** 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.

1. WHAT MYELENEA CONTAINS

Each capsule contains 0,5 mg fingolimod.

The other ingredients are: cellulose capsule shells (containing: carrageenan, hypromellose, iron oxide yellow, potassium chloride, titanium dioxide), magnesium stearate, microcrystalline cellulose, TekPrint black ink (containing: black iron oxide, potassium hydroxide, shellac).

Sugar free.

2. WHAT MYELENEA IS USED FOR

MYELENEA is used in adults to treat Multiple Sclerosis (MS). MS is a long-term condition that affects the central nervous system (CNS), comprised of the brain and spinal cord. In MS, inflammation destroys the protective sheath (called myelin) around the nerves in the CNS and stops the nerves from working properly. Symptoms vary from patient to patient, but typically involve

walking difficulties, numbness, vision problems or disturbed balance. **MYELENEA** is used specifically in:

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

MYELENEA 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.

3. BEFORE YOU TAKE MYELENEA

Do not take MYELENEA:

- If you are hypersensitive (allergic) to fingolimod or any of the other ingredients of **MYELENEA** (see **WHAT MYELENEA CONTAINS).**
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).
- If you are also taking medicine to treat an irregular heartbeat e.g. medicines containing quinidine, procainamide, amiodarone or sotalol.

Take special care with MYELENEA:

- At the beginning of treatment, **MYELENEA** causes 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 pronounced, tell your doctor, because you may need urgent treatment**. MYELENEA** 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.
- Your doctor will ask you to stay at the surgery or clinic for at least 6 hours, with hourly pulse blood pressure measurements, after taking the first dose of **MYELENEA.** You should have an electrocardiogram performed prior to the first dose of **MYELENEA** and after the 6-hour monitoring period. Your doctor may monitor your electrocardiogram continuously during that time. If after the 6-hour period you have a very slow or decreasing heart rate, or if your electrocardiogram shows abnormalities, you may need to be monitored for a longer period (at least 2 more hours and possibly overnight) until these have resolved. The same may

apply if you are resuming **MYELENEA** after a break in treatment, depending on both how long the break was and how long you had been taking **MYELENEA** before the break.

- **MYELENEA** has a slight effect on the lung function. Patients with severe lung problems or with smoker's cough may have a higher chance of developing side effects.

Tell your doctor:

- If you are currently taking medicines that can cause your heart rate to decrease (such as verapamil, diltiazem or digoxin), **MYELENEA** may not be appropriate for you. You will need to be evaluated by a cardiologist who will check whether you can be switched to alternative medicine that does not decrease your heart rate, in order to allow treatment with **MYELENEA**. If such a switch is impossible, the cardiologist will advise how you should start treatment with **MYELENEA**, including overnight monitoring.
- If you notice any skin growths (e.g. shiny pearly nodules), patches or open sores that do not heal within weeks.Symptoms may include abnormal growth or changes of skin tissue (e.g unusual moles) with a change in colour, shape or size over time. Before you start **MYELENEA** a skin examination is required to check whether you have any skin nodules. Your doctor will also carry out regular skin examinations during your treatment with **MYELENEA**. If you develop skin problems your doctor may refer you to a dermatologist, who after consultation may decide that it is important to be seen on a regular basis. Never be exposed to sunlight without protection and you should not receive phototherapy with UV-B-radiation or PUVA-photochemotherapy (used to treat cancer).
- Cases of unusually large brain lesions (damage) associated with MS relapse have been reported in patients treated with **MYELENEA**. In case of severe relapse, your doctor will consider performing ~~a~~ MRI to evaluate this condition and will decide whether you need to stop taking **MYELENEA.**
- If you are planning to get vaccinated, since during and for up to 2 months after treatment with **MYELENEA**, vaccination may be less effective.
- 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.

- If the centre of your vision gets blurry or has shadows, if you develop a blind spot in the centre of your vision or if you have problems seeing colours or fine detail, you may have developed a problem with your vision (macular oedema). Tell your doctor immediately (see **POSSIBLE SIDE EFFECTS**).
- If you notice yellowing of your skin or the whites of your eyes, abnormally dark urine or unexplained nausea and vomiting, tell your doctor immediately.
- **MYELENEA** lowers the white blood cell count (particularly the lymphocyte count). White blood cells fight infection. While you are taking **MYELENEA** (and for up to 2 months after you stop taking it), you may get infections more easily. Any infection that you already have may get worse. Infections could be serious and life-threatening. If you think you have an infection, have fever, feel like you have the flu, or have a headache accompanied by stiff neck, sensitivity to light, nausea, and/or confusion (these may be symptoms of meningitis), contact your doctor immediately.
- **MYELENEA** can cause a slight elevation of blood pressure. Your doctor may want to check your blood pressure regularly.
- A serious brain infection called posterior reversible encephalopathy syndrome (PRES), has been reported in MS patients treated with **MYELENEA**. Symptoms may include sudden onset of severe headache, confusion, seizures (fits), problems with balance and vision changes. Tell your doctor immediately if you experience any of these symptoms during your treatment with **MYELENEA**.

Taking MYELENEA with food and drink:

MYELENEA can be taken with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **MYELENEA.**

Do not take **MYELENEA** if pregnant or breastfeeding.

You should also avoid becoming pregnant while taking **MYELENEA** or in the 2 months after you have stop taking it. Talk to your doctor about reliable methods of birth control that you should use during treatment and for 2 months after stopping
treatment.

Driving and using machinery:

MYELENEA may impair your ability to drive a vehicle or use machines. Take special care before performing tasks requiring your attention, until you know how **MYELENEA** will affect you.

Taking other medicines with MYELENEA:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.) Tell your doctor or pharmacist if you are currently using:

- 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 **MYELENEA**, you should not receive certain types of vaccines (live attenuated vaccines) as they could trigger the infection that they were supposed to prevent. Other vaccines may not work as well as usual if given during this period.
- Medicines that slow the heart beat (for example beta blockers, such as atenolol). Use of **MYELENEA** together with such medicines could intensify the effect on heartbeat in the first days after starting **MYELENEA**.
- Medicines for irregular heartbeat, such as quinidine, disopyramide, amiodarone or sotalol. Your doctor may decide not to prescribe **MYELENEA** if you are taking such a medicine because it could intensify the effect on irregular heartbeat.
- Other medicines e.g. protease inhibitors (antiviral medicine); anti-infectives and antifungals such as ketoconazole, clarithromycin or telithromycin; or carbamazepine,

phenobarbitone, phenytoin (medicines used to treat seizures (fits); rifampicin (used to treat tuberculosis (TB)), efavirenz (used to treat HIV infection) or St. John's Wort (a herbal medicine used to treat mood disorders).

4. HOW TO TAKE MYELENEA

Do not share medicines prescribed for you with any other person. Always take **MYELENEA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one **MYELENEA** 0,5 mg capsule per day, taken with a glass of water. **MYELENEA** can be taken with or without food.

Do not exceed the stated dose.

Your doctor will tell you how long your treatment with **MYELENEA** will last.

If you have the impression that the effect of **MYELENEA** is too strong or too weak, tell your doctor or pharmacist.

If you take more MYELENEA than you should:

In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre. Take this leaflet and the rest of the remaining **MYELENEA** with you so the doctor will know what you have taken.

If you forget to take a dose of MYELENEA:

If you miss a dose of **MYELENEA**, take the next capsule at the scheduled time for the next dose.

Never take a double dose to make up for a forgotten dose.

Effects when treatment with MYELENEA is stopped:

Do not stop taking **MYELENEA** or change your dose without talking to your doctor first.

MYELENEA 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.

5. POSSIBLE SIDE EFFECTS

MYELENEA can have side effects.

Not all side effects reported for **MYELENEA** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **MYELENEA**, please consult your healthcare provider for advice.

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

- Swelling of your hands, feet, ankles, face, lips, 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 allergic reaction to **MYELENEA.** 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:

Frequent:

- 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.

- Liver problems, causing symptoms such as nausea, vomiting, stomach pain, loss of appetite, tiredness, yellowing of your skin or the whites of your eyes, dark urine.
- A type of skin cancer called basal cell carcinoma which often appears as a pearly nodule, although it can also take other forms.
- Slow heartbeat, irregular heart rhythm.

Less frequent:

- Lung infection, with symptoms such as fever, cough, difficulty breathing, shortness of breath, breathlessness.
- Fungal infection, with symptoms such as headache, stiff neck, sensitivity to light, nausea, vomiting, confusion.
- Macular oedema (a problem with your vision). Symptoms include 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).
- A serious brain infection called posterior reversible encephalopathy syndrome (PRES). Symptoms include swelling and narrowing of the blood vessels in your brain, causing symptoms such as sudden headache, confusion, seizures (fits), loss of vision, weakness.
- Malignant melanoma (a type of skin cancer which usually develops from an unusual mole).
- Lymphoma (a type of cancer that affects the lymph system).
- Squamous cell carcinoma (a type of skin cancer which may present as a firm red nodule, a sore with crust, or a new sore on an existing scar).
- Tumor related to infection with human herpes virus 8 (Kaposi’s carcinoma).
- Seizure (Fits).
- Abnormal heart beat that will be seen on an Electrocardiogram (T-wave inversion).

Frequency unknown:

- Risk of a rare brain infection called progressive multifocal leukoencephalopathy (PML). The symptoms of PML may be similar to an MS relapse, or you may experience mood changes, memory loss or speech difficulty.
- Merkel cell carcinoma (a type of skin cancer which may present as a fast growing, painless nodule which may be skin coloured or appear in shades of red, blue or purple).

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

Tell your doctor if you notice any of the following:

Frequent:

- Blood test results showing a low level of white blood cells.
- Headache, dizziness, migraine.
- Sensation of pins and needles in your hands and feet.
- Feeling of pressure or pain in the cheeks and forehead (sinusitis).
- Eye pain, blurred vision.
- Cough.
- Diarrhoea.
- Back pain.
- Feeling weak, with a lack of energy.
- Severe itching of the skin, red, irritated or inflamed skin.
- Hair loss (temporary).
- Infection from flu virus with symptoms such as tiredness, chills, sore throat, aching in the joints or muscles, fever.
- High blood pressure.
- Low mood (depression).
- Pain in a muscle or a group of muscles (myalgia).

- Pain in joints (arthralgia).

Less Frequent:

- Blood test results showing a low level of blood platelet counts.
- Poor circulation in the legs that can cause leg pain (peripheral arterial occlusive disease).
- Nausea.

Frequency unknown:

- Accumulation of fluid causing swelling, usually in the lower limbs (peripheral oedema).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF MYELENEA

- Store at or below 25 °C.
- Protect from moisture.
- Keep blister strips in outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF MYELENEA

Three ply, cold formable silver aluminium plastic / silver push through primer foil, containing 10 capsules each, stored in an outer carton.

Pack size: 30 capsules.

8. IDENTIFICATION OF MYELENEA

Yellow opaque cap / white opaque body, size 3 capsule, imprinted with “A190” on cap in black ink and filled with white to off-white powder.

9. REGISTRATION NUMBER

50/34/0830

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Forrester Pharma (Pty) Ltd

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