

Applicant/PHCR: DR REDDY'S LABORATORIES (PTY) LTD  
Product proprietary name: PHINMO 0,5  
Dosage form: Capsules  
Strength: Each capsule contains 0,5 mg fingolimod (as hydrochloride).

**APPROVED PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S4

**PHINMO 0,5 mg, capsules**

**Fingolimod**

**Sugar free**

**Read all of this leaflet carefully before you start taking PHINMO**

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

**1. What PHINMO is and what it is used for**

PHINMO contains the active substance fingolimod, which belongs to a group of medicines known as sphingosine-1-phosphate (S1-P) receptor modulators. It

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is used in the treatment of relapsing (returning) multiple sclerosis (MS).

PHINMO 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).

### **How PHINMO works**

Multiple sclerosis (MS) is a long-term condition that affects the central nervous system (CNS), particularly how the brain and spinal cord work. In MS, inflammation destroys the protective sheath (called myelin) around the nerves in the CNS, and stops the nerves from working properly.

PHINMO helps to fight against cells that cause inflammation from reaching the brain.

This reduces nerve damage caused by MS.

## **2. What you need to know before you take PHINMO**

### **Do not take PHINMO**

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

### **Warnings and precautions**

#### **Take special care with PHINMO:**

**You will be observed hourly by a health care professional for at least 6 hours**

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after taking the first dose of PHINMO 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 PHINMO 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.

The same recommendation may apply if you start treatment after a break in PHINMO therapy, depending on how long the break is and how long you have been receiving treatment.

Checking the health of your heart is particularly important if any of the following applies to you. Your doctor may decide not to use PHINMO. If your doctor thinks that PHINMO is good for you, he/she may refer you first to a cardiologist (doctor specialised in heart disease). You may also be monitored overnight by a health care professional after taking the first dose of PHINMO.

**Tell your doctor or pharmacist before using PHINMO:**

- If you are taking medicines for an irregular heartbeat such as quinidine, procainamide, amiodarone or sotalol (see “Other medicines and PHINMO”).
- If you have uncontrolled high blood pressure, if when you sleep you are severely affected by interruptions of breathing (sleep apnoea that is not treated). Your doctor may decide not to use PHINMO if you have or have had one of these conditions.
- If you have severe lung problems. PHINMO has a slight effect on the lung function.
- If you suffer from a slow heart rate, if at the start of the treatment with

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PHINMO you are taking medicines that slow your heart rate or if you have a history of sudden loss of consciousness (fainting). Your doctor may decide not to use PHINMO or may refer you first to a cardiologist to switch you to medicines that do not slow your heart rate or to decide how you should be observed after you take the first dose of PHINMO.

At the beginning of treatment, PHINMO can cause the heart rate to slow down.

PHINMO 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. If your heart rate slows down too much or your blood pressure drops, you may need treatment right away. In this case you will be monitored overnight by a health care professional and the same observation process that took place for your first dose of PHINMO will also apply for the second dose of PHINMO.

- If you have no history of chickenpox or have not been vaccinated against **varicella zoster virus**. Your doctor will test your status of the antibody against the virus and may decide to vaccinate you (if you do not have antibodies to this virus). In this case you will start PHINMO treatment one month after the full course of the vaccination is completed.
- Your doctor will consider **whether you need to have a vaccination against Human Papilloma Virus (HPV)** before starting treatment. If you are a female, your doctor will also recommend HPV screening. HPV infection, including papilloma, dysplasia, warts and HPV- related cancer, has been reported in patients treated with PHINMO.
- **If you have a lowered immune response** (due to a disease or medicines that suppress the immune system, see "Other medicines and PHINMO"). You may

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get infections including opportunistic infections more easily or an infection you already have may get worse.

- **If you have an infection, tell your doctor before you take PHINMO.** Any infection that you already have may get worse. Infections could be serious and sometimes life-threatening. Before you start taking PHINMO, your doctor will confirm whether you have enough white blood cells in your blood.
- **If you plan to receive a vaccine.** You should not receive certain types of vaccines (called live attenuated vaccines) during and for up to 2 months after treatment with PHINMO (see Taking other medicines with PHINMO).
- **If you have or have had visual disturbances or other signs of swelling in the central vision area at the back of the eye (a condition known as macular oedema), inflammation or infection of the eye (uveitis) or if you have diabetes.** Your doctor may want you to undergo an eye examination before you start PHINMO and at regular intervals after the start of PHINMO treatment.
- **If you have liver problems.** You will have a blood test to check your liver function before you start taking PHINMO.

PHINMO 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.

If you get any of these symptoms or diseases, during your treatment with PHINMO, **tell your doctor straight away because it could be serious:**

- If you believe your MS is getting worse (e.g. weakness or visual changes) or if you notice any new or unusual symptoms, because these may be the symptoms of a rare brain disorder caused by an infection and called progressive multifocal leukoencephalopathy (PML).
- If you think you have an infection, have fever, feel like you have the flu or have

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a headache accompanied by stiff neck, sensitivity to light, nausea, and/or confusion (these may be caused by a fungal infection and be symptoms of cryptococcal meningitis).

- A condition called posterior reversible encephalopathy syndrome (PRES) has been reported in MS patients treated with PHINMO. Symptoms may include sudden onset of severe headache, confusion, seizures and vision changes.
- A condition with unusually large brain lesions associated with MS relapse has been rarely reported in patients treated with PHINMO (a condition called tumefactive lesions). In case of severe relapse, your doctor will consider performing an MRI scan to evaluate this condition and will decide whether you need to stop taking PHINMO.
- A type of skin cancer called **basal cell carcinoma (BCC) and other cutaneous neoplasms** such as malignant melanoma, squamous cell carcinoma, Kaposi's sarcoma and Merkel cell carcinoma have been reported in MS patients treated with PHINMO. Your doctor will carry out regular skin examinations during your treatment with PHINMO. Symptoms of BCC may include skin nodules (e.g. shiny pearly nodules), patches or open sores that do not heal within weeks. Symptoms of other cutaneous neoplasms may include abnormal growth or changes of skin tissue (e.g. unusual moles) which may present as a change in colour or size over time.

Long- term exposure to the sun and a weak immune system can affect the risk of developing Merkel cell carcinoma. You should limit your exposure to the sun and UV rays by wearing appropriate protective clothing and regularly apply sunscreen with a high degree of UV protection.

- A type of cancer of the lymphatic system (lymphoma) has been reported in MS patients treated with PHINMO.

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### **Switch from other treatments to PHINMO**

Your doctor may switch you directly from beta interferon, glatiramer acetate or dimethyl fumarate to PHINMO if there are no signs of abnormalities caused by your previous treatment. Your doctor may have to do a blood test in order to exclude such abnormalities. After stopping natalizumab you may have to wait for 2-3 months before starting treatment with PHINMO. To switch from teriflunomide, your doctor may advise you to wait for a certain time or to go through an accelerated elimination procedure. If you have been treated with alemtuzumab, a thorough evaluation and discussion with your doctor is required to decide if PHINMO is appropriate for you.

**Tell your doctor straight away**, if you get any of the following symptoms or diseases **after you have stopped your treatment** with PHINMO because it could be serious:

- If you believe your MS is getting worse.

### **Older people** (over 65 years old)

Experience with PHINMO in older people is limited. Talk to your doctor if you have any concerns.

### **Children and adolescents** (under 18 years old)

PHINMO is not intended for use in children and adolescents, as it has not been studied in MS patients aged under 18.

### **Other medicines and PHINMO**

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- **Medicines for an irregular heartbeat** such as, quinidine, procainamide, amiodarone or sotalol. You must not use PHINMO if you are taking such a medicine (see "Do not take PHINMO").
- **Medicines that slow down heartbeat** such as beta-blockers (such as

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atenolol), calcium channel blockers (such as verapamil or diltiazem) or ivabradine or digoxin. Your doctor may decide not to use PHINMO 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 PHINMO.

- **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 PHINMO, 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.
- **Other medicines:**
  - protease inhibitors, anti-infectives such as ketoconazole, azole antifungals, clarithromycin or telithromycin.
  - carbamazepine, rifampicin, phenobarbital, phenytoin, efavirenz or St. John's Wort (potential risk of reduced efficacy of PHINMO).

Tell your doctor or a pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **Taking PHINMO with food and drink**

You can take PHINMO with or without food.

### **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

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before receiving this medicine.

### **Pregnancy**

**You should avoid becoming pregnant while taking PHINMO or in the two months after you stop taking it** because of the risks of harm to the baby. Talk to your doctor about the associated risks and about reliable methods of birth control that you should use during treatment and for 2 months after you stop treatment.

Therefore, if you are a female who could become pregnant, before you start treatment with PHINMO, your doctor:

- will tell you about the risk to an unborn baby,
- will ask you to do a pregnancy test in order to ensure that you are not pregnant, and
- you should use effective contraception while taking PHINMO and for two months after you stop taking it.

Tell your doctor if you are pregnant, think you might be pregnant, or are trying to become pregnant.

**If you do become pregnant while taking PHINMO tell your doctor right away.** You and your doctor will decide what is best for you and your baby. See also section 3 – “How to take PHINMO – If you stop taking PHINMO”

### **Breastfeeding**

**You should not breastfeed your baby while you are taking PHINMO.** PHINMO can pass into breast milk and there is a risk of serious side effects for a breastfed baby. Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breastfeeding.

### **Driving and using machines**

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely. Driving may be impaired by some of the side-effects of PHINMO.

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### **3. How to take PHINMO**

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

Always take PHINMO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. **Do not exceed the recommended dose.**

#### **How much PHINMO to take**

The dose is one capsule per day (0,5 mg of fingolimod).

#### **How and when to take PHINMO**

Take PHINMO once a day, with half a glass of water. PHINMO can be taken with or without food.

Taking PHINMO at the same time each day will help you remember when to take your medicine.

#### **How long to take PHINMO**

Do not stop taking PHINMO or change your dose without talking with your doctor.

If you have questions about how long to take PHINMO, talk to your doctor or your pharmacist.

#### **If you take more PHINMO than you should or if you have taken a first dose of PHINMO by mistake**

If you take too much PHINMO at one time, or if you have taken a first dose of PHINMO by mistake, contact your doctor or pharmacist right away.

Your doctor may decide to observe you with heart rate and blood pressure measurements every hour, to run ECGs and he may decide to monitor you overnight. If neither is available, contact the nearest hospital or poison control centre.

#### **If you forget to take PHINMO**

If you forget a dose, take the next dose as planned. Do not take a double dose to make up for a forgotten dose.

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If you have been taking PHINMO for less than 2 weeks and you forgot to take a dose for one day, contact your doctor right away. Your doctor may decide to observe you at the time you take the next dose.

#### **If you stop taking PHINMO**

Do not stop taking PHINMO or change your dose without talking with your doctor.

After PHINMO treatment is stopped, symptoms of MS can return and may become worse compared to before or during treatment. Tell your doctor if you have worsening of MS symptoms after stopping PHINMO.

PHINMO 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 are a woman, see "Pregnancy and breast feeding".

If you have stopped PHINMO for 1 day or more during the first 2 weeks of PHINMO treatment, if you stop for more than 7 days during weeks 3 and 4 of treatment, or if you stop taking PHINMO for more than 2 weeks after your first month of PHINMO treatment, the initial effect on your heart rate may occur again. When you restart PHINMO treatment, your doctor may decide to monitor your heart rate and blood pressure every hour, to run ECG's or to keep you under monitoring overnight.

#### **4. Possible side effects**

PHINMO can have side effects.

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

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

- Swelling of the 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 PHINMO. 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:**

**Serious side effects include:**

Frequent side effects:

- Bronchitis with symptoms such as cough with phlegm, chest pain, fever
- Shingles (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, and red patches, with severe pain
- Slow heartbeat (bradycardia)
- A type of skin cancer called basal cell carcinoma (BCC) which often appears as a pearly nodule, though it can also take other forms.

Less frequent side effects:

- Pneumonia with symptoms such as fever, cough, difficulty breathing
- Macular oedema (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
- Melanoma, a type of skin cancer usually developing from an unusual mole

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(nevus). Possible signs of melanoma include moles which may change size, shape, elevation or colour over time, or new moles. The moles may itch, bleed or ulcerate.

- A condition called posterior reversible encephalopathy syndrome (PRES). Symptoms may include sudden onset of severe headache, confusion, seizures and vision changes.
- Tumour related to infection with human herpes virus 8 (Kaposi's sarcoma).

Frequency unknown:

- Serious irregularity in heart beat that is temporary
- A rare brain disorder caused by infection and called progressive multifocal leukoencephalopathy (PML). The symptoms of PML may be similar to MS (e.g. weakness or visual changes).
- Cryptococcal infections (a type of fungal infection), including cryptococcal meningitis with symptoms such as headache accompanied by stiff neck, sensitivity to light, nausea, and/or confusion.
- After PHINMO treatment is stopped, symptoms of MS can return and may become worse compared to before or during treatment.
- Autoimmune form of anaemia (decreased amount of red blood cells) where red blood cells are destroyed (autoimmune haemolytic anaemia)
- HPV infection, including papilloma, dysplasia, warts and HPV- related cancer.

If you experience any of these, **tell your doctor straight away.**

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:

- Infection from flu virus with symptoms such as tiredness, chills, sore throat, joint or muscles aching, fever
- Headache

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- Diarrhoea
- Back pain
- Blood testing showing higher levels of liver enzymes
- Cough
- Feeling of pressure or pain in the cheeks and forehead (sinusitis)
- Ringworm, a fungal infection of the skin (tinea versicolor)
- Dizziness
- Severe headache often accompanied by nausea, vomiting and sensitivity to light (signs of migraine)
- Weakness
- Itchy, red, burning rash (signs of eczema)
- Itchy skin
- Blood fat (triglycerides) level increased
- Breathlessness
- Abnormal lung function test results starting after one month of treatment, remaining stable after that and reversible after treatment discontinuation
- Blurred vision (see "Tell your doctor or pharmacist before using PHINMO:")
- Hypertension. PHINMO may cause a mild increase in blood pressure
- Low level of white blood cells (lymphopenia, leukopenia).

Frequency unknown:

- 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
- Nausea
- Muscle pain
- Joint pain
- Weight loss.

If any of these affects you severely, **tell your doctor.**

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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 “**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 PHINMO.

### 5. How to store PHINMO

- Store at or below 25 °C, protect from moisture.
- PHINMO 0,5 mg capsules must always be stored in the blister to protect from moisture and only be removed immediately before use. The blisters should be kept in the carton until required for use.
- Store all medicines out of reach of children.
- Do not use PHINMO after the expiry date which is stated on the label and carton.
- 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 PHINMO contains

- The active substance is fingolimod.

PHINMO 0,5: Each capsule contains 0,5 mg fingolimod (as hydrochloride).

- The other ingredients are:

Capsule contents: Betacyclodextrin (Betadex), magnesium stearate

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Capsule shell: Iron oxide yellow (E172), titanium dioxide (E171),  
gelatin, sodium lauryl sulphate, water

Printing ink: Shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol,  
propylene glycol, strong ammonia solution, black iron oxide,  
potassium hydroxide, purified water

#### **What PHINMO looks like and contents of the pack**

##### PHINMO 0,5

White to off-white powder filled in size '3' hard gelatin capsules with  
with dark yellow opaque colored cap imprinted 'FGM' with black ink and white opaque  
colored body imprinted '0.5 mg' with black ink.

##### Blister packs

7 or 10 capsules per blister made of PVC/Aclar film and aluminium foil. The aluminium  
foil is silver and the PVC/Aclar film is clear and transparent. The outer container is a  
printed cardboard box.

Pack sizes are 7, 10, 14, 28 or 98.

Not all pack sizes may be marketed.

#### **Holder of Certificate of Registration**

Dr. Reddy's Laboratories (Pty) Ltd

Block B, 204 Rivonia Road

Morningside

Sandton

2057

#### **This leaflet was last revised in**

13 June 2023

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#### **Registration numbers**

55/34/0851

#### **Access to the corresponding Professional Information**

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty)

Ltd. website: <http://www.drreddys.co.za>

For any information about this medicine, please contact the local representative of the

Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100