Fingolimod SUN
The Patient/Parent/Caregiver guide

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

- Patients should read the package leaflet thoroughly before starting treatment and should keep it in case they need to refer to it again during treatment.
- Please refer to the Consumer Medicine Information (CMI) for full details on the safe use of this medicine.

About Fingolimod SUN

- **What FINGOLIMOD is and how it works**

  Fingolimod SUN contains the active substance FINGOLIMOD, which belongs to a group of medicines known as sphingosine 1-phosphate (S1-P) receptor modulators. FINGOLIMOD can alter the way the body's immune system works and is used in adults, children and adolescents (10 years of age and above) to treat relapsing remitting multiple sclerosis (MS).

Understanding Multiple Sclerosis (MS)

- **What multiple sclerosis is**
  - 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 cover around the nerves (called myelin) and stops the nerves from working properly.
  - The cause of MS is unknown but it is thought that an abnormal response by the body's immune system plays an important part in the process which damages the CNS.
  - This medicine slows down the progression of physical disability and decreases the number of flare-ups (relapses) in patients with relapsing MS.

Importance of Reporting Adverse Reactions

- Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product.
- Adverse reactions can be reported to Sun Pharma ANZ through email: adverse.events.aus@sunpharma.com or phone: 1800 726 229 or directly to TGA. https://www.tga.gov.au/safety/reporting-problems.

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Important Information for Patients, Parents, and Caregivers

Immune Reconstitution Inflammatory Syndrome (IRIS)

- Patients should be aware that, in rare cases, immune reconstitution inflammatory syndrome (IRIS) may occur during or after treatment. If you notice any new or worsening symptoms, seek medical advice promptly.

Blood Tests Before Starting Treatment

- Your doctor will perform a complete blood count (CBC) before starting treatment with fingolimod to ensure it is safe for you to begin therapy.

Vaccination and Physical Development Monitoring Requirements (Paediatric Patients)

- Paediatric patients should complete their full vaccination schedule prior to starting fingolimod treatment, in accordance with local immunisation guidelines.
- Paediatric patients will undergo assessment of physical development

Vaccinations During Treatment

- Speak with your doctor about vaccinations before and during treatment. Some vaccines may not be suitable while taking fingolimod, and timing of vaccination may need to be adjusted.

Contraindications and precautions

Contraindications:

- hypersensitivity to the active substance or to any of the excipients
- known immunodeficiency syndrome
- increased risk for opportunistic infections. This also applies to immunocompromised patients (including those currently receiving immunosuppressive therapies or those immunocompromised by prior therapies).
- severe active infections, active chronic infections (hepatitis, tuberculosis)
- known active malignancies
- severe liver impairment (Child-Pugh class C)
- myocardial infarction (MI), unstable angina pectoris, stroke/transient ischaemic attack (TIA), decompensated heart failure (requiring inpatient treatment), or New York Heart Association (NYHA) class III/IV heart failure in the previous 6 months.
- severe cardiac arrhythmias requiring anti-arrhythmic treatment with class Ia or class III anti arrhythmic drugs.
- second-degree Mobitz type II atrioventricular (AV) block or third-degree AV block, or sick sinus syndrome, if the patient does not wear a pacemaker.
- a baseline QTc interval ≥500 msec.

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Precautions:

- *Infections*

  Fingolimod causes a dose-dependent reduction in peripheral lymphocyte count to 20 – 30% of baseline values because of reversible sequestration of lymphocytes in lymphoid tissues (see section 5 Pharmacological properties). Fingolimod may therefore increase the risk of infections, including opportunistic infections, some serious in nature.

- *Vaccination*

  Vaccination may be less effective during and for up to two months after stopping treatment with fingolimod. The use of live attenuated vaccines should be avoided.

- *Macular Oedema*

  Macular oedema can occur with or without visual symptoms. An ophthalmologic evaluation should be performed before starting fingolimod and at 3-4 months after treatment initiation. Monitor visual acuity at baseline and during routine evaluations of patients.

- *Bradyarrhythmia*

  Initiation of fingolimod treatment results in a decrease in heart rate. After the first dose, the heart rate decrease starts within an hour and the Day 1 decline is maximal within 6 hours (see section 5 Pharmacological properties [Pharmacodynamics - Heart rate and rhythm]). In patients receiving fingolimod 0.5 mg, this decrease in heart rate, as measured by pulse, averages approximately 8 beats per minute (bpm)

- *First dose monitoring*

  on initiation of fingolimod treatment, it is recommended that all patients be observed, with hourly pulse and blood pressure measurement, for a period of 6 hours for signs and symptoms of bradycardia.

- *Liver function*

  Increased liver enzymes, mostly alanine aminotransaminase (ALT) elevation, have been reported in multiple sclerosis patients treated with fingolimod.

- *Posterior reversible encephalopathy syndrome*

  Rare cases of posterior reversible encephalopathy syndrome (PRES) have been reported at 0.5 mg dose in clinical trials and in the post-marketing setting.

- *Skin Cancers*

  Skin cancers including basal cell carcinoma (BCC), malignant melanoma, squamous cell carcinoma, Kaposi's sarcoma and Merkel cell carcinoma, have been reported in patients receiving fingolimod.

- *Lymphomas*

  There have been cases of lymphoma in clinical studies and the post-marketing setting.

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Monitoring and Assessments

- Patients should have a baseline ECG and blood pressure measurement prior to receiving the first dose of FINGOLIMOD.
- Patient's doctor may arrange an eye assessment before starting FINGOLIMOD as well as a follow-up eye assessment 3-4 months after starting treatment.
- Patient's doctor will arrange magnetic resonance imaging (MRI) scans before the treatment starts and during treatment to monitor the risk of progressive multifocal leukoencephalopathy (PML).
- Heart rate should be monitored for 6 or more hours after the first dose of FINGOLIMOD, including hourly pulse and blood pressure checks. Patients may be monitored with continuous ECG during the first 6 hours. An ECG at 6 hours should also be performed and, in some circumstances, monitoring may involve an overnight stay.
- Patients should call their doctor in case of treatment interruption as the first dose monitoring may need to be repeated, depending on duration of interruption and time since starting of FINGOLIMOD treatment.

Cardiac and First Dose Effects

Patients should report immediately symptoms indicating low heart rate (such as dizziness, vertigo, nausea or palpitations) after the first dose of FINGOLIMOD.

- FINGOLIMOD is not recommended in patients with cardiac disease or those taking medicines concomitantly known to decrease heart rate, and they should tell any doctor they see that they are being treated with FINGOLIMOD.

Infection Risk and Monitoring

Signs and symptoms of infection, which should be immediately reported to the prescribing physician during and up to two months after FINGOLIMOD treatment, including the following:

  - Headache accompanied by stiff neck, sensitivity to light, fever, flu-like symptoms, nausea, rash, shingles and/or confusion or seizures (fits) (may be symptoms of meningitis and/or encephalitis, either caused by a fungal or viral infection).

Your doctor will monitor your white blood cell (lymphocyte) counts during treatment with FINGOLIMOD. Treatment with FINGOLIMOD may be interrupted if your lymphocyte count is too low.

Neurological Risks (Including PML)

Symptoms such as weakness, visual changes, changes in mood or behaviour, confusion, memory lapses, speech and communication difficulties or new/worsening MS symptoms (may be symptoms of progressive multifocal leukoencephalopathy [PML]).

Visual Effects

- Any symptoms of visual impairment should be reported immediately to the prescriber during and for up to two months after the end of treatment with FINGOLIMOD.

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Cancer and Screening

- The need to undergo cancer screening, including a Pap test, and vaccination for HPV-related cancer, as per standard of care, will be assessed by the prescribing physician.
- Skin cancers have been reported in MS patients treated with FINGOLIMOD. Patients should inform their doctor immediately if any skin nodules (e.g., shiny, pearly nodules), red patches or open sores that do not heal within weeks are noted. Symptoms of skin cancer may include abnormal growth or changes of skin tissue (e.g., unusual moles) with a change in colour, shape or size over time.

Pregnancy and Reproductive Health

FINGOLIMOD is teratogenic. Women of child-bearing potential, including adolescent females, should:

- Be informed before treatment initiation and regularly thereafter by their physician about FINGOLIMOD's serious risks to the foetus, and about the contraindication in pregnant women and in women of childbearing potential not using effective contraception, facilitated by the pregnancy-specific patient reminder card.
- Have a negative pregnancy test before starting FINGOLIMOD.
- Be using effective contraception during and for at least two months following discontinuation of FINGOLIMOD treatment.
- Report immediately to the prescribing physician any (intended or unintended) pregnancy during and up to two months following discontinuation of FINGOLIMOD treatment.

Liver Monitoring

- A liver function test should be performed prior to treatment initiation; liver function monitoring should be performed at months 1, 3, 6, 9 and 12 during FINGOLIMOD therapy, and periodically thereafter; until 2 months after FINGOLIMOD discontinuation. Patients should inform their doctor if they notice yellowing of their skin or the whites of their eyes, abnormally dark urine, pain on the right side of the stomach area, tiredness, feeling less hungry than usual or unexplained nausea and vomiting as these can be signs of liver injury.

Seizures

- Seizure may occur. The doctor should be informed about a pre-existing history or family history of epilepsy.

Treatment Discontinuation

- Stopping FINGOLIMOD therapy may result in return of disease activity. The prescribing physician should decide whether and how the patient should be monitored after stopping FINGOLIMOD.

Specifically for Paediatric patients:

The following should be considered:

- Physicians should assess Tanner staging and measure height and weight as per standard of care;
- Precautions should be taken during the first dose of FINGOLIMOD and when patients are switched from 0.25 to 0.5 mg daily;
- Depression and anxiety are known to occur with increased frequency in the MS population and have been reported also in paediatric patients treated with FINGOLIMOD;

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- Cardiac monitoring guidance;
- Patients should ensure medication compliance and avoid misuse, especially treatment interruption, and repeat cardiac monitoring;
- Signs and symptoms of infection;
- Seizures may occur during treatment. Inform the doctor if there is a family history of epilepsy.

Things to remember about Fingolimod SUN

This medicine is under additional monitoring; consequently, patients are encouraged to report side effects:

"If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the CMI. You can also report side effects directly via http://www.tga.gov.au/reporting-problems. By reporting side effects you can help provide more information on the safety of this medicine."

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Medical Information and to report adverse events: adverse.events.aus@sunpharma.com or 1800 726 229.
Date of preparation: May 2026 FIN08/2024PAGU