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.

- 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).
- 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.
- 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.
- 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.
- Patients should have a baseline ECG and blood pressure measurement prior to receiving the first dose of FINGOLIMOD.
- 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.
- Patients should report immediately symptoms indicating low heart rate (such as dizziness, vertigo, nausea or palpitations) after the first dose of FINGOLIMOD.

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- 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.
- Signs and symptoms of infection, which should be immediately reported to the prescriber 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);.
  - Symptoms such as weakness, visual changes, or new/worsening MS symptoms (may be symptoms of progressive multifocal leukoencephalopathy [PML]).
- The need to undergo cancer screening, including Pap test, and vaccination for HPV-related cancer, as per standard of care, will be assessed by the prescriber physician.
- 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.

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;

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

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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;
- Cardiac monitoring guidance;
- Patients should ensure medication compliance and avoid misuse, especially treatment interruption, and repeat cardiac monitoring;
- Signs and symptoms of infection;
- Seizure monitoring guidance.

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.
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