

**Fingolimod**  
(Gilenya®)

Patient Information

Updated: 10.2019

USED FOR	<ul style="list-style-type: none"> <li>Relapsing forms of multiple sclerosis (MS)</li> <li>Fingolimod will not cure MS. It may reduce flare-ups and slow the disease progression.</li> </ul>
HOW IT WORKS	<ul style="list-style-type: none"> <li>Fingolimod works by keeping the immune system's white blood cells in the lymph nodes, so they don't travel to the brain to attack the myelin and cause injury to the nervous system.</li> </ul>
BEFORE STARTING FINGOLIMOD	<ul style="list-style-type: none"> <li>You will need a complete blood count, liver function tests, an eye exam, and a test to check the electrical activity of your heart (ECG).</li> <li>You will need blood tests to ensure that you have immunity to chickenpox. If you don't have immunity to chickenpox, it is advised that you get the varicella (chickenpox) vaccine at least 1 month before starting Fingolimod.</li> <li>Tell your doctor if you are taking medicines for: heart problems, high blood pressure or medicines that may lower your heart rate or change your heart rhythm</li> </ul>
FIRST DOSE OBSERVATION (FDO)	<ul style="list-style-type: none"> <li>When you take your first dose, you need observed for at least 6 hours by a medical provider at a doctor's office or medical facility because Fingolimod can initially cause your heart rate to slow down (it will recover in 1 month). This is called the First Dose Observation (FDO).</li> <li>Before making an appointment for your FDO, you must get authorization from your insurance.</li> <li>During the FDO, your heart rate will be checked every hour for 6 hours. If your heart rate is too low, you might be observed for a longer time.</li> <li>Upon successful completion of the FDO, you will be given 2 weeks of FREE Fingolimod and the rest of the supply will be shipped to your home.</li> </ul>
DOSE	<ul style="list-style-type: none"> <li>One capsule (0.5 milligrams) taken by mouth once a day.</li> </ul>
HOW IT IS GIVEN	<ul style="list-style-type: none"> <li>Fingolimod is taken every day at the same time of day with or without food. It is very important that you do not forget to take this medication.</li> </ul>
WHAT HAPPENS IF YOU MISS DOSES?	<ul style="list-style-type: none"> <li>You will have to repeat the FDO if you miss too many doses:             <ul style="list-style-type: none"> <li>&gt; 1 day, within the first 2 weeks</li> <li>&gt; 7 days, during weeks 3 and 4</li> <li>&gt; 2 weeks, after 4 weeks</li> </ul> </li> </ul>

HOW IT IS SUPPLIED	<ul style="list-style-type: none"> <li>Fingolimod 0.5 mg hard gelatin capsule</li> <li>Fingolimod 0.25 mg capsule (for pediatric patients <math>\leq 40</math> kg)</li> </ul> 
STORAGE	<ul style="list-style-type: none"> <li>Fingolimod may be kept at room temperature. Keep the medication away from direct sunlight, extreme heat, or cold.</li> </ul>
SIDE EFFECTS	<ul style="list-style-type: none"> <li>COMMON <ul style="list-style-type: none"> <li>Slowed heart rate (with the initial dose that will resolve after 1 month)</li> <li>Increased blood pressure</li> <li>Abnormal liver tests</li> <li>Low white blood cells</li> </ul> </li> <li>SERIOUS, BUT RARE <ul style="list-style-type: none"> <li>AV block and bradyarrhythmia (heart rate that is too slow causing serious effects)</li> <li>Infection, including viruses like chicken pox</li> <li>Progressive multifocal leukoencephalopathy (PML), a rare brain infection that can occur and usually leads to death or severe disability. <ul style="list-style-type: none"> <li>⇒ Call your doctor right away if you have new or worsening medical problems that last several days or problems with thinking, eye sight, strength, balance, weakness on 1 side of the body, or using your arms and legs.</li> </ul> </li> <li>Vision problems called macular edema (higher risk if you have diabetes or inflammation of your eye called uveitis)</li> <li>Skin cancer (basal cell carcinoma)</li> <li>Liver damage</li> </ul> </li> </ul>
DRUG INTERACTIONS	<ul style="list-style-type: none"> <li>Avoid taking with medicines that can change your heart rhythm or heart rate</li> <li>Some seizure medications (Carbamazepine) and antifungal medicines can strongly interact with Fingolimod</li> <li>Live or live-attenuated vaccines should be avoided during treatment with Fingolimod as their safety for MS is unclear. Fingolimod may decrease the effectiveness of vaccines.</li> </ul>
MONITORING	<ul style="list-style-type: none"> <li>You will need a follow-up eye exam every 3-6 months to make sure you haven't developed macular edema, and then once yearly.</li> <li>You will need a repeat complete blood count and liver tests at 3, 6, 9, and 12 months for the first year, then every 6 months to 1 year.</li> <li>You will need a brain MRI with and without contrast at 6 months</li> <li>Your doctor may request a yearly skin exam with a dermatologist</li> </ul>
MORE INFORMATION	<ul style="list-style-type: none"> <li>Websites: <a href="http://www.nationalmssociety.org">www.nationalmssociety.org</a>, <a href="http://www.gilenya.com">www.gilenya.com</a></li> <li>Clinical Trials: <ul style="list-style-type: none"> <li>Cohen JA, et al. N Engl J Med. 2010;362(5):402-15.</li> <li>Kappos L, et al. N Engl J Med. 2010;362(5):387-401.</li> </ul> </li> </ul>

This information is for educational purposes only and is not intended to replace the advice of your doctor or health care provider. We encourage you to discuss with your doctor any questions or concerns you may have.