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## Fingolimod

pronounced as (fin gol' i mod)

### Why is this medication prescribed?

Fingolimod is used to prevent episodes of symptoms and slow the worsening of disability in adults and children 10 years of age and older with relapsing-remitting forms (course of disease where symptoms flare up from time to time) of multiple sclerosis (MS; a disease in which the nerves do not function properly and people may experience weakness, numbness, loss of muscle coordination, and problems with vision, speech, and bladder control). Fingolimod is in a class of medications called sphingosine I-phosphate receptor modulators. It works by decreasing the action of immune cells that may cause nerve damage.

### How should this medicine be used?

Fingolimod comes as a capsule to take by mouth. It is usually taken once a day with or without food. Take fingolimod at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take fingolimod exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Fingolimod may cause the heartbeat to slow in adults and children, especially during the first 6 hours after you take your first dose, and after the first dose when the dose is increased in children. You will receive an electrocardiogram (ECG; test that records the electrical activity of the heart) before you take your first dose and again 6 hours after you take the dose. You will take your first dose of fingolimod in your doctor's office or another medical facility. You will need to stay at the medical facility for at least 6 hours after you take the medication so that you can be monitored. You may need to stay at the medical facility for longer than 6 hours or overnight if you have certain conditions or take certain medications that increase the risk that your heartbeat will slow or if your heartbeat slows more than expected or continues to slow after the first 6 hours. You may also need to stay at a medical facility for at least 6 hours after you take your second dose if your heartbeat slows too much when you take your first dose. Tell your doctor if you experience dizziness, tiredness, chest pain, or slow or irregular heartbeat at any time during your treatment, especially during the first 24 hours after you take your first dose.

Fingolimod may help control multiple sclerosis but will not cure it. Do not stop taking fingolimod without talking to your doctor. If you do not take fingolimod for 1 day or longer during the first 2 weeks of treatment, for 1 week or longer in the third and fourth weeks of treatment or for 2 weeks or longer after the first month of treatment, talk to your doctor before you start taking it again. You may experience

slowed heartbeat when you start taking fingolimod again, so you will need to restart the medication in your doctor's office.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with fingolimod and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking fingolimod,

- tell your doctor and pharmacist if you are allergic to fingolimod. If you have had a serious allergic reaction to fingolimod or any of the ingredients in fingolimod capsules (rash, hives, swelling of the face, eyes, mouth, throat, tongue, lips, hands, feet, ankles, or lower legs), your doctor will probably tell not to fingolimod. Also, tell your doctor if you are allergic to any other medications, or any of the ingredients in fingolimod capsules. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor if you are taking medications for irregular heartbeat such as amiodarone (Nexterone, Pacerone), disopyramide (Norpace), dofetilide (Tikosyn), dronedarone (Multaq), ibutilide (Corvert), procainamide, quinidine (in Nuedexta), and sotalol (Betapace, Sorine, Sotylyze). Your doctor will probably tell you not to take fingolimod if you are taking one or more of these medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take during your treatment with fingolimod. Be sure to mention any of the following: beta-blockers such as atenolol (Tenormin, in Tenoretic), carteolol, labetalol (Trandate), metoprolol (Lopressor, Toprol-XL, in Dutoprol, in Lopressor HCT), nadolol (Corgard, in Corzide), nebivolol (Bystolic, in Byvalson), propranolol (Inderal LA, Innopran XL), and timolol; diltiazem (Cardizem, Cartia, Tiazac, others); chlorpromazine; citalopram (Celexa); digoxin (Lanoxin); erythromycin (E.E.S., Ery-Tab, PCE, others); haloperidol (Haldol); ketoconazole; medications for heart problems; methadone (Dolophine, Methadose); and verapamil (Calan, Verelan, in Tarka). Also tell your doctor if you are taking any of the following medications, or if you have taken them in the past: corticosteroids such as dexamethasone, methylprednisolone, and prednisone; medications for cancer; and medications to weaken or control the immune system such as mitoxantrone, natalizumab (Tysabri), and teriflunomide (Aubagio). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with fingolimod, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you have or have had any of these conditions in the last six months: heart attack, angina (chest pain), stroke or mini-stroke, or heart failure. Also tell your doctor if you have long QT syndrome (condition that increases the risk of developing an irregular heartbeat that may cause fainting or sudden death) or irregular heart rhythm. Your doctor may tell you not to take fingolimod.
- tell your doctor if you have ever fainted, had a heart attack, stroke, or mini stroke, or if you currently have a fever or other signs of infection, if you have an infection that comes and goes or that does not go away, and if you have or have ever had diabetes; sleep apnea (condition in which you briefly stop

breathing many times during the night) or other breathing problems; high blood pressure; uveitis (inflammation of the eye) or other eye problems; a slow heartbeat; low levels of potassium or magnesium in your blood; skin cancer, or heart or liver disease. Also tell your doctor if you have recently received a vaccine.

- tell your doctor if you are pregnant or plan to become pregnant, or are breastfeeding. You should use birth control to prevent pregnancy during your treatment and for 2 months after your final dose. If you become pregnant while taking fingolimod or within 2 months after your final dose, call your doctor.
- do not have any vaccinations during your treatment with fingolimod or for 2 months after your final dose without talking to your doctor. Talk to your child's doctor about vaccinations that your child may need to receive before beginning his or her treatment with fingolimod.
- tell your doctor if you have never had chicken pox and have not received the chicken pox vaccine. Your doctor may order a blood test to see if you have been exposed to chicken pox. You may need to receive the chicken pox vaccine and then wait one month before beginning your treatment with fingolimod.
- plan to avoid unnecessary or prolonged exposure to sunlight and UV light (such as tanning booths) and to wear protective clothing, sunglasses, and sunscreen. Fingolimod may make your skin more sensitive to the dangerous side effects of sunlight, and may increase your risk of developing skin cancer.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and call your doctor before you take the next dose. You may need to be monitored as you restart your medication. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Fingolimod may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- weakness
- back pain
- pain in the hands or feet
- diarrhea
- abdominal pain
- nausea
- headache or migraine
- hair loss

**Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:**

- slow heartbeat
- rash, hives, itching; swelling of the face, eye, mouth, throat, tongue or lips; or difficulty swallowing or breathing
- sore throat, body aches, fever, chills, cough, and other signs of infection and during treatment and for 2 months after your treatment
- headache, neck stiffness, fever, sensitivity to light, nausea, or confusion during treatment and for 2 months after your treatment
- painful, burning, numb, or tingling feeling on skin, sensitivity to touch, rash, or itching during treatment and for 2 months after your treatment
- sudden severe headache, confusion, changes in vision, or seizures
- blurriness, shadows, or a blind spot in the center of your vision; sensitivity to light; unusual color to your vision or other vision problems
- changes to an existing mole; a new darkened area on skin; sores that do not heal; growths on your skin such as a bump that may be shiny, pearly white, skin-colored, or pink, or any other changes to your skin
- weakness on one side of the body or clumsiness of the arms or legs that worsens over time; changes in your thinking, memory, or balance; confusion or personality changes; or loss of strength
- new or worsening shortness of breath
- nausea, vomiting, loss of appetite, abdominal pain, yellowing of skin or eyes, or dark urine

Fingolimod may increase the risk of developing skin cancer and lymphoma (cancer that begins in the cells that fight infection). Talk to your doctor about the risks of taking this medication.

A sudden increase episodes of MS symptoms and worsening of disability may occur within 3 to 6 months after you stop taking fingolimod. Tell your doctor if your MS symptoms worsen after stopping fingolimod.

Fingolimod may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

## **What should I know about storage and disposal of this medication?**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org>

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p> ]) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## Symptoms of overdose may include the following:

- slowed or irregular heartbeat

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests, and skin and eye exams, and will monitor your blood pressure before and during your treatment to be sure that it is safe for you to begin taking or continue to take fingolimod.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking fingolimod.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Gilenya®

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