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2. Fingolimod

# Fingolimod

**Generic name:** fingolimod [ *fin-GOE-li-mod* ]

**Brand names:** [Gilenya](#), [Tascenso ODT](#)

**Dosage forms:** oral capsule (0.25 mg; 0.5 mg), oral tablet, disintegrating (0.25 mg; 0.5 mg)

**Drug class:** [Selective immunosuppressants](#)



[Medically reviewed](#) by Drugs.com on Jun 22, 2023. Written by [Cerner Multum](#).

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## What is fingolimod?

Fingolimod is used in adults and children at least 10 years old to treat relapsing forms of [multiple sclerosis](#) (including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease).

Fingolimod may also be used for purposes not listed in this medication guide.

## Fingolimod side effects

Get emergency medical help if you have **signs of an allergic reaction**: hives, difficult breathing, swelling of your face, lips, tongue, or throat.

Fingolimod may cause a brain infection that can lead to disability or death. Tell your doctor if you have problems with speech, thought, vision, or muscle movement. These symptoms can get worse quickly.

Fingolimod can affect your immune system (even 2 months after you've taken fingolimod). **You may get infections more easily, even serious or fatal infections.** Call your doctor if you have:

- **signs of a new infection**--fever, night sweats, swollen glands, cold sores, cough, wheezing, diarrhea, [weight loss](#);
- trouble speaking or swallowing, problems with balance or eye movement, weakness or prickly feeling; or
- swelling in your neck or throat (enlarged thyroid), menstrual changes, impotence.

Also call your doctor at once if you have:

- new darkened area on your skin, a sore that does not heal, a mole that has changed in size or color, a bump that looks shiny, pearly, or pink;
- vision problems such as increased sensitivity to light, blurred vision, having a blind spot or shadows in the center of your vision, or unusual color to your vision (may occur 3 to 4 months after you start taking fingolimod);
- new or worsened breathing problems;

- sores in your mouth and throat, cold sores, sores on your genital or anal area;
- new or worsening symptoms of multiple sclerosis at least 12 weeks after your last dose;
- sudden confusion, severe headache, weakness, vision loss, or seizure;
- increased blood pressure;
- a light-headed feeling, like you might pass out;
- **heart problems**--chest pain, slow or irregular heartbeats, and feeling dizzy or tired; or
- **liver problems**--nausea, loss of appetite, stomach pain (upper right side), tiredness, itching, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes).

**Common side effects of fingolimod may include:**

- headache, back pain;
- stomach pain, diarrhea;
- pain in your arms or legs;
- cough, stuffy nose, flu symptoms; or
- abnormal liver function tests.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

 [Fingolimod side effects](#) (more detail)

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## Warnings

**You should not use fingolimod if you take certain heart rhythm medicines, or if you've had a serious heart condition in the past 6 months.** Serious heart conditions include certain heart rhythm disorders, [heart failure](#), chest pain, [heart attack](#), or stroke.

Fingolimod can slow your heart rate when you start taking it. You will receive your first dose in a setting where your heart rhythm can be monitored. **Tell your doctor if you have slow heartbeats, chest pain, shortness of breath, or feel like your heart is skipping beats.**

**You may get infections more easily, even serious or fatal infections.** Call your doctor if you have flu symptoms, cough, night sweats, neck stiffness, confusion, vision problems, increased sensitivity to light, [loss of balance](#) or coordination, or weakness on one side of the body. **Your risk of infection could last for 2 months after you stop**

## taking this medicine.

You may have increased sensitivity to light, blurred vision, eye pain, or have a blind spot or shadows in the center of your vision, unusual color to your vision, or other vision problems while you are taking fingolimod, which may occur 3 to 4 months after your first dose.

## Before taking this medicine

You should not use fingolimod if you are allergic to it, or if you have:

- severe heart failure (that required you to be in the hospital);
- a serious heart condition such as "sick sinus syndrome" or "AV block" (unless you have a pacemaker);
- [long QT syndrome](#); or
- recent (within the past 6 months) heart attack, stroke, "mini-stroke" or TIA, chest pain ([unstable angina](#)), or other serious heart problem.

**Some heart rhythm medications can cause unwanted or dangerous effects when used with fingolimod.** Your doctor may change your treatment plan if you also use: amiodarone, [disopyramide](#), dofetilide, flecainide, [dronedarone](#), ibutilide, mexiletine, [procainamide](#), [propafenone](#), quinidine, or sotalol.

**Before you take fingolimod, tell your doctor if you have never had chickenpox or received a varicella vaccine (Varivax).** You may need to receive the vaccine and then wait 1 month before taking fingolimod.

Make sure you are current on all vaccines before you start taking fingolimod.

**Tell your doctor if you have recently received a vaccine, or if you are scheduled to receive a vaccine.**

Tell your doctor if you have ever had:

- fever or an active or chronic infection;
- a weak immune system (caused by disease or by using certain medicine);
- a heart rhythm disorder;
- chest pain (angina) or other heart problems;
- a heart attack or stroke, including "mini-stroke";
- [high blood pressure](#);
- fainting;
- diabetes;
- skin cancer;
- [sleep apnea](#), or other breathing disorder;
- an eye condition called uveitis; or
- [liver disease](#).

**Fingolimod may harm an unborn baby. Do not use if you are pregnant.** Use effective [birth control](#) while taking fingolimod and for at least 2 months after your last dose. Tell your doctor if you become pregnant.

If you are pregnant, your name may be listed on a pregnancy registry to track the effects of fingolimod on the baby.

Ask a doctor if it is safe to breastfeed while taking fingolimod.

## How should I take fingolimod?

Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose. Use the medicine exactly as directed.

Fingolimod can slow your heart rate when you start taking it. You will receive your first dose in a medical setting. **Your blood pressure and heart rate will be constantly monitored for at least 6 hours after your first dose of fingolimod.**

You may need medical tests before and while taking fingolimod including blood tests, tests to check your heart function, blood pressure, vision exams, liver function tests and skin exams.

Take fingolimod once per day with or without food.

Remove an **orally disintegrating tablet** from the blister pack with dry hands only when you are ready to take the medicine. Take this medicine immediately after opening the blister pack. Allow the **orally disintegrating tablet** to dissolve in your mouth without chewing.

If you stop taking this medicine, do not start it again without your doctor's advice.

**Your condition may get worse if you stop taking fingolimod suddenly.** Ask your doctor before stopping the medicine.

**You may get infections more easily, even serious or fatal infections.**

Store fingolimod in the original container at room temperature away from moisture and heat.

This medicine can affect the results of certain medical tests. Tell any doctor who treats you that you are taking fingolimod.

## Fingolimod dosing information

### Usual Adult Dose for Multiple Sclerosis:

0.5 mg orally once a day

#### Comments:

-This drug can be taken with or without food.

-See DOSE ADJUSTMENTS for recommended pre-dose testing and monitoring recommendations.

Use: For relapsing forms of multiple sclerosis (MS)

### Usual Pediatric Dose for Multiple Sclerosis:

10 years and older and weighing 40 kg or less:

0.25 mg orally once a day

10 years and older and weighing more than 40 kg:

0.5 mg orally once a day

Comments:

-This drug can be taken with or without food.

-See DOSE ADJUSTMENTS for recommended pre-dose testing and monitoring recommendations.

Use: For relapsing forms of multiple sclerosis (MS) in patients 10 years and older

 [Detailed Fingolimod dosage information](#)

## What happens if I miss a dose?

Call your doctor for instructions. **If you miss one or more doses, you may need to take your next dose in a medical setting.**

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

## What should I avoid while taking fingolimod?

Fingolimod can increase your risk of skin cancer. Avoid sunlight or tanning beds. Wear protective clothing and use sunscreen (SPF 30 or higher) when you are outdoors.

**Avoid receiving a "live" vaccine while taking fingolimod**, and for at least 2 months after your treatment ends. The vaccine may not work as well while you are taking fingolimod. **Receiving a "live" vaccine while taking fingolimod may cause you to develop a serious infection.** Live vaccines include measles, mumps, rubella (MMR), rotavirus, typhoid, yellow fever, varicella (chickenpox), and zoster (shingles).

## What other drugs will affect fingolimod?

**Sometimes it is not safe to use certain medicines at the same time.** Some drugs can affect your blood levels of other drugs you use, which may increase side effects or make the medicines less effective.

**Fingolimod can cause a serious heart problem.** Your risk may be higher if you also use certain other medicines for infections, asthma, heart problems, high blood pressure, depression, mental illness, cancer, malaria, or HIV.

Fingolimod can have long lasting effects on your body, especially on your immune system. For 2 months after your last dose, tell any doctor who treats you that you have taken fingolimod.

**Tell your doctor about all your current medicines.** Many drugs can affect fingolimod, especially:

- drugs that weaken the immune system such as cancer medicine, steroids, and medicines to prevent [organ transplant](#) rejection;
- [ketoconazole](#); or
- heart medications.

**This list is not complete and many other drugs may affect fingolimod.** This includes prescription and over-the-counter medicines, vitamins, and [herbal products](#). Not all possible [drug interactions](#) are listed here.

 [Fingolimod drug interactions](#) (more detail)

## Does fingolimod interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

+

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Patient resources

Other brands

[Gilenya](#), [Tascenso ODT](#)

Professional resources

- [Fingolimod Hydrochloride \(Sytemic\) monograph](#)
- [Fingolimod \(FDA\)](#)

Other brands

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Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

[Medical Disclaimer](#)

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DRUG STATUS

| Availability  |                       |
|---|-----------------------|
| Rx  | Prescription only     |
| Pregnancy & Lactation   |                       |
|  | Risk data available   |
| CSA Schedule*   |                       |
| N/A   | Not a controlled drug |
| Approval History  |                       |
|  | Drug history at FDA   |

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[Fingolimod Hydrochloride 0.5 mg \(base\) \(912\)](#)



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