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# Gilenya

**Pronunciation:** *je-LEN-yah*

**Generic name:** [fingolimod](#)

**Dosage form:** capsules

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

Medically reviewed by [Philip Thornton, DipPharm](#). Last updated on Jun 20, 2024.

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## What is Gilenya?

Gilenya (fingolimod) belongs to a class of medications called sphingosine 1-phosphate receptor modulators. Fingolimod works by decreasing the action of immune cells that may cause nerve damage.

Gilenya 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). It is taken by mouth (orally).

Gilenya will not cure MS, it will only decrease the frequency of relapse symptoms.

Gilenya was FDA-approved on September 21, 2010.

## Gilenya side effects

**Common Gilenya side effects may include:**

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

## Serious side effects

Get emergency medical help if you have **signs of an allergic reaction to Gilenya**: hives, difficulty 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 this medicine). 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, or a bump that looks shiny, pearly, or pink. The **risk of certain skin cancers**, such as basal cell carcinoma and melanoma, is increased in people who take S1P receptor modulators such as Gilenya;
- **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 Gilenya). S1P receptor modulators, including Gilenya, have been associated with an increased risk of macular edema. Your healthcare provider should send you for an eye examination before starting treatment, 3 to 4 months into treatment, periodically thereafter, and any time there is a vision change. Patients with diabetes or a history of uveitis are more at risk;
- 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).

Longer treatment durations of Gilenya (more than 18 months) increase the risk of developing progressive multifocal leukoencephalopathy (PML), **a rare brain infection**.

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.

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

## Related/similar drugs

### Copaxone

Copaxone is used to treat relapsing forms of multiple sclerosis (MS) in adults (including ...

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## Reviews & ratings

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## Warnings

**You should not use Gilenya 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 Gilenya, which may occur 3 to 4 months after your first dose.

## Before taking this medicine

You should not use Gilenya if you are allergic to fingolimod, 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 problems.

Some heart rhythm medications can cause unwanted or dangerous effects when used with Gilenya. 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 Gilenya, 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 this medicine.

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

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

To make sure Gilenya is safe for you, 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 medicines);
- 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 it if you are pregnant.** Use effective [birth control](#) while taking Gilenya 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 this medicine.

 [Gilenya pregnancy and breastfeeding warnings](#) (more detail)

## How should I take Gilenya?

Take Gilenya exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose.

Gilenya 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 Gilenya.**

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

Take Gilenya 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 Gilenya suddenly. Ask your doctor before stopping the medicine.

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

Store 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 this medicine.

 [Gilenya patient tips](#) (more detail)

## 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 Gilenya 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 Gilenya?

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 Gilenya, and for at least 2 months after your treatment ends. The vaccine may not work as well while you are taking this medicine. Receiving a "live" vaccine while taking Gilenya 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 Gilenya?

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.

Gilenya 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 Gilenya.

Tell your doctor about all your current medicines. Many drugs can interact with 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 interact with fingolimod. This includes prescription and over-the-counter medicines, [vitamins](#), and [herbal products](#). Not all possible drug interactions are listed here.

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

## Does Gilenya interact with my other drugs?

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

Gilenya

+

Enter a drug name

Add

## Ingredients

### 0.25 mg capsules

**Active ingredient:** fingolimod

**Inactive ingredients:** mannitol, hydroxypropylcellulose, hydroxypropylbetadex, magnesium stearate, gelatin, titanium dioxide, yellow iron oxide.

### 0.5 mg capsules

**Active ingredient:** fingolimod

**Inactive ingredients:** mannitol, magnesium stearate, gelatin, titanium dioxide, yellow iron oxide.

## Manufacturer

**Manufactured by:** Novartis Pharma Stein AG Stein, Switzerland.

**Distributed by:** Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936, USA.



## Popular FAQ

Gilenya vs Tecfidera. How do they compare?



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## References

1. [Gilenya Product Label](#)

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## Patient resources

### Other brands

[Tascenso ODT](#)

## Professional resources

- [Gilenya prescribing information](#)
- [Fingolimod Hydrochloride \(Sytemic\) \(AHFS Monograph\)](#)

### Other brands

[Tascenso ODT](#)

## Related treatment guides

- [Multiple Sclerosis](#)

## Further information

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

[Medical Disclaimer](#)

### DRUG STATUS

#### Availability

**Rx** Prescription only

#### [Pregnancy & Lactation](#)

 Risk data available

#### CSA Schedule\*

**N/A** Not a controlled drug



#### Approval History

**10+ years** FDA approved 2010



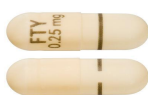
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## Images

Gilenya 0.5 mg (FTY 0.5 mg)



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