



# Gilenya

Generic Name: fingolimod (fin GOE li mod)

**Brand Names**: Gilenya

Medically reviewed by P. Thornton, DipPharm Last updated on Jan 22, 2019.

## What is Gilenya?

Gilenya (fingolimod) is an immunosuppressant. It works by keeping immune cells trapped in your lymph nodes so they can't reach the central nervous system (brain and spinal cord).

Gilenya is used to treat relapsing multiple sclerosis (MS) in adults, and children and adolescents aged 10 years and older.

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

### **Important Information**

You should not use Gilenya if you have a serious heart condition. This includes severe heart failure, "AV block," sick sinus syndrome (unless you have a pacemaker), taking certain heart rhythm medicines, or a recent heart attack, stroke, chest pain, or other serious heart problem.

Fingolimod can slow your heart rate. You will receive your first dose in a hospital setting where your heart rhythm can be monitored.

Gilenya affects your immune system. You may get infections more easily, even serious or fatal infections. Call your doctor if you have a fever, chills, aches, tiredness, vomiting, confusion, neck stiffness, increased sensitivity to light, or problems with speech, thought, vision, or muscle movement.

#### Before taking this medicine

You should not use Gilenya if you are allergic to fingolimod, or if you have certain serious heart conditions, especially:

- severe heart failure (that required you to be in the hospital);
- "AV block" or sick sinus syndrome (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 Gilenya, tell your doctor if you have never had **chickenpox** or if you have never received a varicella vaccine (**Varivax**). You may need to receive the vaccine and then wait 1 month before taking this medicine.

Tell your doctor if you have ever had:

- an active or chronic infection;
- a very slow heart rate;
- high or low blood pressure;
- heart problems, a heart attack, a stroke, or chest pain;
- fainting spells;
- · diabetes:
- · liver or kidney disease;
- an eye condition called uveitis; or
- asthma, sleep apnea, or other breathing disorder.

Using Gilenya may increase your risk of developing skin cancer (melanoma). Ask your doctor about skin symptoms to watch for.

**Fingolimod may harm an unborn baby.** Use effective **birth control** to prevent pregnancy while you are using this medicine, and for at least 2 months after your last dose. Tell your doctor if you become pregnant during this time.

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

You should not breast-feed while using fingolimod.

#### 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 will perform medical tests to make sure you do not have conditions that would prevent you from safely using Gilenya.

Fingolimod can slow your heart rate. You will receive your first dose in a hospital setting. Your blood pressure and heart rate will be constantly monitored for at least 6 hours after your first dose of Gilenya.

You may take Gilenya with or without food.

If you stop taking Gilenya, do not start taking it again without asking your doctor. You will need to be under medical observation when you restart this medication

Always ask your doctor before you stop taking Gilenya for any reason. When you stop taking this medicine, your MS symptoms may return. In rare cases, some people who stopped taking fingolimod had MS symptoms that were worse than before or during treatment with this medicine.

If you stop taking Gilenya, watch for signs of worsening MS for at least 12 weeks after your last dose. Call your doctor right away if any new or worsening symptoms appear.

Gilenya affects your immune system. You may get infections more easily, even serious or fatal infections. Your doctor will need to examine you on a regular basis. Your risk of infection could last up to 2 months after you stop taking this medicine.

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

### **Gilenya dosing information**

**Usual Adult Dose for Multiple Sclerosis:** 

0.5 mg orally once daily

Comments: Monitor with first dose (see WARNINGS section).

Use: For the treatment of patients with relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

See also:

Gilenya dosage information (in more detail)

# What happens if I miss a dose?

Call your doctor for instructions. If you miss 1 or more doses, you may need to take your next dose under medical observation 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?

Gilenya 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.

Do not receive a "live" vaccine while using fingolimod, and for 2 months after your last dose. The vaccine may not work as well during this time, and may not fully protect you from disease. Live vaccines include **measles**, mumps, **rubella** (MMR), polio, rotavirus, typhoid, yellow fever, varicella (chickenpox), or zoster (**shingles**).

# Gilenya side effects

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

Gilenya may cause a serious brain infection that can lead to disability or death. Call your doctor right away if you have problems with speech, thought, vision, or muscle movement. These symptoms may start gradually and get worse quickly.

Also call your doctor at once if you have:

- chest pain, slow or irregular heartbeats, dizziness, tiredness;
- shiny nodules on your skin, sores that do not heal, unusual moles that change in color or size;
- fever, chills, body aches, tiredness, nausea and vomiting, neck stiffness, increased sensitivity to light;
- sores in your mouth and throat, cold sores, sores on your genital or anal area;
- vision problems, blurred vision, eye pain, or having a blind spot or shadows in the center of your vision (vision problems may occur 3 to 4 months after you start taking this medicine);
- headache, confusion, change in mental status, vision loss, seizure (convulsions);
- · shortness of breath; or
- liver problems nausea, upper stomach pain, tiredness, loss of appetite, dark urine, jaundice (yellowing of the skin or eyes).

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.

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.

#### See also:

Gilenya side effects (in more detail)

### What other drugs will affect Gilenya?

**Gilenya 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**.

Tell your doctor about all the other medicines you take, especially:

• drugs that weaken the immune system such as cancer medicine, steroids, and medicines to prevent organ transplant rejection.

Many drugs can interact with fingolimod. This includes prescription and over-the-counter medicines, **vitamins**, and **herbal products**. Not all possible interactions are listed here. Tell your doctor about all your current medicines and any medicine you start or stop using.

#### See also:

Gilenya drug interactions (in more detail)

#### **Further information**

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

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

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#### **Related questions**

What are the new drugs for the treatment of multiple sclerosis (MS)?