

## Patient Medication Information

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

**Pr GILENYA®**

#### Fingolimod capsules

This patient medication information is written for the person who will be taking **GILENYA®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **GILENYA**, talk to a healthcare professional.

#### What GILENYA is used for:

GILENYA is used to treat:

- Adults with relapsing and remitting multiple sclerosis (MS): With this type of MS, new symptoms can appear, or existing symptoms can get worse during flare-ups (relapses). Between relapses, recovery is complete or almost complete. GILENYA is recommended for people who have not responded well to or who cannot tolerate other treatments.
- Children and adolescents (ages 10 to under 18) with relapsing MS.

#### How GILENYA works:

GILENYA does not cure MS, but it helps by:

- reducing the number of flare-ups (relapses).
- lessening inflammation in the brain and spinal cord (seen on MRI scans) that can damage nerves.
- slowing down the worsening of physical problems caused by MS.

GILENYA changes how your immune system works by making it harder for certain white blood cells (lymphocytes) to move around your body. This lowers the number of these cells in your blood and keeps them from reaching your brain and spinal cord. As a result, this may help lessen the inflammation and nerve damage that happens with MS.

#### The ingredients in GILENYA are:

Medicinal ingredient: fingolimod (as fingolimod hydrochloride)

Non-medicinal ingredients: gelatin, hydroxypropylbetadex (0.25 mg capsule), hydroxypropylcellulose (0.25 mg capsule), magnesium stearate, mannitol, titanium dioxide and yellow iron oxide.

#### GILENYA comes in the following dosage forms:

Hard capsules: 0.25 mg and 0.5 mg

#### Do not use GILENYA if:

- you are allergic to fingolimod or to any of the other ingredients in GILENYA (see **The ingredients in GILENYA are:**).
- your immune system is weakened because of:

- disease like immunodeficiency syndrome.
- treatments like cancer medicines or bone marrow transplantation.
- you currently have a severe infection or long-term infection such as hepatitis or tuberculosis (TB).
- you currently have cancer, but it is not the type of skin cancer called basal cell carcinoma.
- you have serious liver disease.
- you have heart problems, like:
  - a heart attack, chest pain (angina), stroke or signs of a stroke, or certain types of heart failure in the last 6 months.
  - certain types of irregular or abnormal heartbeat (arrhythmia), or prolonged QT interval on your heart test (ECG).
- you are taking or have recently taken medicine for irregular heartbeat such as quinidine, disopyramide, amiodarone or sotalol, which may affect your heartbeat.
- you are pregnant, think you might be pregnant or plan to get pregnant.
- you are of childbearing age and are not using effective birth control.
- you are of childbearing age until a pregnancy test confirms that you are not pregnant. This test is done just before you start GILENYA.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take GILENYA. Talk about any health conditions or problems you may have, including if:**

- you have or have had heart issues like:
  - high or low blood pressure.
  - a slow heart rate.
  - already taking other medicines that slow your heart rate.
  - or having fainted before.
- you have severe untreated sleep apnea. This is a condition where your breathing repeatedly starts and stop while you sleep.
- you have a weakened immune system because of a disease or other medicines or treatments you are receiving.
- you got a vaccine within 1 month before starting GILENYA or plan to get one. Avoid certain types of vaccines (called “live attenuated vaccines”) during and for up to 2 months after treatment with GILENYA.
- your child (10 years to under 18 years of age) has not finished their vaccination schedule. They need to complete it before starting GILENYA.
- you have never had chickenpox or have not been vaccinated for it.
- you have had infections like hepatitis or tuberculosis (TB).
- you have or have had eye problems like:
  - eyesight issues or swelling in a part of your eye called the macula.
  - inflammation or infection of the eye (uveitis).
- you have diabetes.
- you have issues with your liver or kidneys.
- you have high level of cholesterol or fat in your blood.
- you have breathing problems.
- you are breastfeeding.
- you are 65 years of age or older. You may have a higher risk of side effects.

**Other warnings you should know about:**

- **Chickenpox:** If you have not had chickenpox or the chickenpox vaccine, you could get a serious and life-threatening chickenpox infection during treatment with GILENYA. Very rarely, chickenpox infections have been deadly in people taking GILENYA along with relatively long course of corticosteroid treatments. Your healthcare professional may recommend getting the chickenpox vaccine 1 month before starting GILENYA.
- **Human Papilloma Virus (HPV):** Your healthcare professionals will let you know if you need an HPV vaccine before starting GILENYA. If you are a woman they will recommend an HPV test. People using GILENYA have reported HPV infection, which can cause:
  - finger-like growths on the skin and mucous membranes (papilloma).
  - abnormal cells in the lower part of the uterus (dysplasia), found by a screening test (PAP smear) in women.
  - warts (small bumps on the skin) and cancer.
- **Blood Tests and Monitoring:** Before you start taking GILENYA and during treatment, your healthcare professional will do tests to check for side-effects. Tests you may need include:
  - blood tests to check:
    - your white blood cell counts.
    - your liver health (see **Liver Problems** below).
  - eye exams to look for eye problems (see **Eye Problems** below).
  - possibly lung function tests.
  - heart rhythm and blood pressure checks.

Because fingolimod can affect your heart (see **Heart Problems** below), you will need a heart test (ECG) before starting fingolimod. If your child is switching from the 0.25 mg capsule to the 0.5 mg capsule, they will also need an ECG. After taking the first dose, you will need to stay in the clinic for at least 6 hours so your heart rate and blood pressure can be checked every hour. A second ECG will be done after 6 hours. Depending on the results, you may need to stay longer, possibly overnight, for checking. This process may also apply if you restart treatment after a break.
- **Heart Problems:** GILENYA can slow down your heart rate, especially in the first month. It can also cause an irregular heartbeat, especially after the first dose or when switching doses (from the 0.25 mg capsule to the 0.5 mg capsule). Irregular heartbeat usually returns to normal in less than one day. Slow heart rate usually returns to normal within one month. People with heart disease or those taking certain medicines are at higher risk. People aged 65 and older are also at higher risk.
  - If you have an irregular heartbeat or a history of fainting, your condition may temporarily worsen with GILENYA. This might also happen if you have a slow heart rate or are taking medicines which slow the heartbeat.
  - If you experience symptoms like dizziness, palpitations (rapid or irregular heartbeat), fainting, or seizures while taking GILENYA, seek immediate medical help.
- **Liver Problems:** GILENYA may cause liver damage. Tell your healthcare professional right away if you have any of the following symptoms of liver problems:
  - nausea
  - vomiting

- stomach pain
  - tiredness
  - loss of appetite
  - your skin or the whites of your eyes turn yellow
  - dark urine
- **Infections:** GILENYA can make it harder for your body to fight infections. This means you may get infections more easily while taking it and for up to 2 months after stopping. If you have an infection before starting GILENYA, tell your healthcare professional, as it could get worse. Infections can be serious and sometimes life-threatening.
    - Before starting GILENYA, your healthcare professional will check your white blood cell count.
    - While taking GILENYA, if you think you have an infection, have a fever, feel like you have the flu, or have a headache with a stiff neck, sensitivity to light, nausea, confusion, or seizures, tell your healthcare professional right away. These could be signs of brain inflammation (encephalitis) or meningitis caused by a serious fungal or viral infection.
    - If you think your MS is getting worse (e.g., weakness or vision changes) or notice any new or unusual symptoms, talk to your healthcare professional as soon as possible. These could be signs of a rare serious brain disorder called progressive multifocal leukoencephalopathy (PML) that is caused by an infection. Your healthcare professional might do an MRI scan to check for this condition and decide if you need to stop GILENYA. After stopping GILENYA because of PML, your healthcare professional will watch for signs of immune reconstitution inflammatory syndrome (IRIS). IRIS is a condition that can occur with PML. It can worsen your condition rapidly and might be life-threatening. Tell your healthcare professional right away if your MS symptoms become worse after stopping GILENYA.
    - Avoid using other medications that affect the immune system while taking GILENYA, as they can increase the risk of infections.
  - **Eye Problems:** When you start GILENYA, you may get a problem with your eyesight called macular edema. It can cause eyesight issues similar to those during an MS attack, like optic neuritis. Sometimes, you may not notice any symptoms. Macular edema usually starts within the first 3 to 4 months of taking GILENYA. Your healthcare professional will check your eyesight around this time, or any time you notice any vision changes. Your risk of macular edema is higher if you have diabetes or have had an inflammation of the eye called uveitis. If you have had eyesight problems, diabetes, uveitis, or other signs of swelling in the central vision area at the back of the eye called macula, your healthcare professional should check your eyesight before you start GILENYA.
  - **Seizures:** Some people have had seizures (fits) while taking GILENYA. It is not clear if the seizures were caused by their MS, GILENYA, or both. If you have a seizure while taking GILENYA, get medical help right away.
  - **Depression and Suicidal Thoughts:** People with MS can have depression and suicidal thoughts. If you are taking GILENYA, you, your family, and caregivers should watch for these symptoms. Tell your healthcare professional right away if any of these symptoms occur.
  - **Cancer Risk:** Taking GILENYA can increase your risk of developing cancers like lymphoma and skin cancer.

- **Watch for Changes:** While you are taking GILENYA, you should check your skin regularly. If you already have moles or open sores before starting GILENYA, watch for changes, keep an eye on them. Look for changes in the size, shape or color of moles or if the open sores do not heal within weeks after you start GILENYA. These may be signs of skin cancer and you should talk to your healthcare professional about them.
- **Types of Skin Cancer:** The types of skin cancer reported in patients taking Gilenya include:
  - Basal cell carcinoma (BCC): Look for shiny, pearly nodules or open sores that don't heal within weeks.
  - Other skin cancer like malignant melanoma, squamous cell carcinoma, Kaposi's sarcoma and Merkel cell carcinoma: Look for changes, such as unusual moles that may change in color, shape or size over time.
- **Regular Checks:** Your healthcare professional will regularly check your skin during your treatment.
- **Sun Exposure:** Long-term exposure to the sun and UV rays, and a weak immune system can affect the risk of a type of skin cancer called Merkel cell carcinoma. Protect yourself by wearing appropriate clothing and regularly applying sunscreen with a high UV protection.
- **Return of MS Symptoms:** After you stop GILENYA, your MS symptoms can come back and may be worse than before or during treatment. If your MS symptoms get worse after stopping GILENYA, tell your healthcare professional right away.
- **Brain Lesions:** Rarely, during an MS relapse or flare-up, people taking GILENYA may get unusually large brain lesions, known as tumefactive lesions. If you have a severe flare-up, your healthcare professional may request an MRI scan to check for this condition and decide if you should stop GILENYA.
- **Blood Disorders:** GILENYA may cause the following blood problems:
  - Breakdown of red blood cells (autoimmune hemolytic anemia): You may feel weak, look pale, or feel tired.
  - Low levels of platelets (thrombocytopenia): You may bruise easily, have bleeding from a cut that is hard to stop, have heavier periods, bleed from your gums or nose, or see small, red, pink, or purple spots on your skin.
 If you notice any of these symptoms, tell your healthcare professional right away.
- **Pregnancy:**
  - Do **not** take GILENYA if you are pregnant. It can harm your unborn baby.
  - If you could become pregnant or are planning to become pregnant, before you start GILENYA your healthcare professional will:
    - explain the risk to your unborn baby.
    - ask you to do a pregnancy test.
    - discuss birth control options with you. You must use effective birth control while you are taking GILENYA and for two months after stopping it.
  - If you become pregnant while taking GILENYA tell your healthcare professional right away. Together, you will decide what is best for you and your baby.
- **Breastfeeding:** Do not breastfeed while taking GILENYA. GILENYA can pass into breast milk and may cause serious side effects for your baby.

- **Driving and using machines:**

- After the first dose of GILENYA, you will be monitored in a medical setting for at least 6 hours to check your heart rate and blood pressure.
- Your ability to drive and use machines may be affected during and possibly after this period. Do not drive or operate machinery until you know how you respond to GILENYA.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

Serious drug interactions:

Do **not** take GILENYA if you are taking, or have recently taken, medicines for an irregular heartbeat such as:

- quinidine
- disopyramide
- amiodarone
- sotalol

**The following may interact with GILENYA:**

- Medicines for heart problems or high blood pressure.
- Medicines that slow down the heartbeat such as atenolol or metoprolol (called beta-blockers), verapamil, or diltiazem (called calcium channel blockers) or ivabradine or digoxin.
- Medicines to treat fungal infections, such as ketoconazole.
- Antibiotics, used to treat bacterial infections, such as erythromycin.
- Medicines used to treat HIV infection.
- Medicines used to treat asthma.
- Medicines that suppress or change the immune system including other medicines used to treat MS (beta-interferon, glatiramer acetate, natalizumab, mitoxantrone, dimethyl fumarate, teriflunomide, alemtuzumab or corticosteroids) or medicines used to treat cancer.
  - Do not start GILENYA while you are on these medications.
  - If you are switching to GILENYA from another MS treatment, your healthcare professional may wait for several months to reduce the added effect on your immune system and the risk of serious infections.
- Vaccines.
  - If you need a vaccine, talk to your healthcare professional first.
  - While you are taking GILENYA and for up to 2 months after stopping it some vaccines with live virus (live attenuated vaccines) may cause the infection that they are meant to prevent.
  - Other vaccines may not work well enough to protect you.

**How to take GILENYA:**

- Always take GILENYA exactly as your healthcare professional has told you.
- Do not stop taking GILENYA or change your dose without talking to your healthcare professional.

- Take GILENYA once a day, at the same time each day with half a glass of water. You can take GILENYA with or without food.
- GILENYA will stay in your body for up to 2 months after you stop it. The side effects described in this leaflet may still occur during that time.

**Usual dose:**

- **Adults:** One 0.5 mg capsule per day.
- **Children and adolescents (10 years to under 18 years):**
  - body weight equal to or below 40 kg: One 0.25 mg capsule per day.
  - body weight above 40 kg: One 0.5 mg capsule per day.

When your child reaches 40 kg, your healthcare professional will discuss increasing the dose from 0.25 mg to 0.5 mg once a day. This change must be done in a medical setting where your child can be closely monitored. Do not change your child's dose without speaking to your healthcare professional.

- **Children (under 10 years old):** GILENYA has not been studied in children under 10 years of age

**Overdose:**

If you think you, or a person you are caring for, have taken too much GILENYA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Take the medication package with you when you go to the hospital.

**Missed dose:**

- If you forget a dose, skip it and take the next dose as planned. Do not take a double dose to make up for a missed one.
- If you miss one dose during the first 2 weeks, or stop taking GILENYA for more than 7 days during weeks 3 and 4, tell your healthcare professional right away. They may decide to monitor you when you take the next dose.
- If you stop taking GILENYA for 2 weeks or more, you will need to restart it in a medical setting. Do not restart GILENYA after stopping it for more than two weeks without talking to your healthcare professional.

**Possible side effects from using GILENYA:**

These are not all the possible side effects you may have when taking GILENYA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Flu virus infection
- Headache
- Diarrhea
- Back pain
- Cough
- Sinusitis (sinus infection)
- Fungal infections affecting skin, nails or hair

- Dizziness
- Migraine
- Weakness
- Mild increase in blood pressure
- Skin rash
- Hair loss
- Itchy skin
- Weight loss
- Blurred vision
- Breathlessness
- Tingling or numbness
- Depression
- Eye pain
- Nausea
- Muscle pain
- Joint pain

#### Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the drug and get immediate medical help
	Only if severe	In all cases	
Common			
<b>Bronchitis:</b> cough with phlegm, chest pain, fever		✓	
<b>Gastroenteritis:</b> vomiting, nausea, diarrhea, fever		✓	
<b>Shingles (herpes zoster infection):</b> blisters, burning, itching or pain of the skin (typically on the upper body or the face), fever, followed by numbness, itching or red patches with severe pain		✓	
<b>Bradycardia (slow heartbeat):</b> feeling dizzy, tired, awareness of own heartbeat, low blood pressure (dizziness, fainting, light-headedness, especially when you got from lying or sitting to standing)		✓	
<b>Skin Cancer:</b> shiny pearly nodules, moles, patches or open sores that changes in size, shape or colour or do not heal, red or brown blotches or tumours usually on the skin of the legs or face		✓	



Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the drug and get immediate medical help
	Only if severe	In all cases	
<b>Low Levels of White blood cells:</b> symptoms of infection (fever, sore throat, mouth ulcers, flu-like feeling)		✓	
<b>Uncommon</b>			
<b>Pneumonia:</b> fever, cough, difficulty breathing		✓	
<b>Macular Edema:</b> shadows or blind spot in the center of the vision, blurred vision, problems seeing colors or fine details		✓	
<b>Liver Problems:</b> nausea, vomiting, loss of appetite, swelling and/or pain in the abdomen, feeling tired, itching, yellowing of the skin or eyes, dark urine		✓	
<b>Shortness of breath</b>		✓	
<b>Seizures (fits)</b> (more frequent in children and adolescents than in adults)			✓
<b>Thrombocytopenia (low levels of platelets):</b> easy bruising, bleeding from a cut that is hard to stop, heavier menstrual periods than normal, bleeding from your gums or nose, small, scattered spots on your skin that are red, pink, or purple		✓	
<b>Rare</b>			
<b>Stroke:</b> weakness and/or loss of feeling of limbs or face, difficulty speaking, clumsiness, vision loss			✓
<b>Peripheral Artery Disease (poor circulation in the limbs):</b> cold, painful, discolored limb, fingers or toes			✓
<b>Posterior Reversible Encephalopathy Syndrome (PRES):</b> sudden severe headache, nausea, vomiting, confusion, drowsiness, personality change, paralysis, abnormal speech, seizures (fits), vision changes			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the drug and get immediate medical help
	Only if severe	In all cases	
<b>Lymphoma (cancer of the lymphatic system):</b> painless swelling of lymph node, swollen tonsils, fever, chills, night sweats, feeling tired, itching, unexplained weight loss, loss of appetite, persistent coughing/ difficulty breathing or not being able to breathe, headache		✓	
<b>Very rare</b>			
<b>Heart Problems:</b> dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, seizures (fits)			✓
<b>Unknown</b>			
<b>Encephalitis and/or meningitis (inflammation of your brain/of the membranes covering your brain, which may be caused by Cryptococcus, a type of fungus, or the herpes simplex or chickenpox viruses):</b> headache with a stiff neck, sensitivity to light, nausea, confusion, seizures (fits)		✓	
<b>Progressive Multifocal Leukoencephalopathy (PML) (a rare brain infection):</b> weakness on one side of your body, problems thinking, vision changes		✓	
<b>Human Papilloma Virus (HPV) Infection:</b> papilloma (finger-like growths on the skin and mucous membranes), dysplasia (abnormal cells in the lower part of the uterus, found by a screening test (PAP smear) in women), warts (small bumps on the skin). All of these can be caused by HPV and can lead to cancer		✓	
<b>Allergic Reactions:</b> rash or itchy hives, swelling of lips, tongue or face, difficulty swallowing or breathing			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the drug and get immediate medical help
	Only if severe	In all cases	
<b>Autoimmune Hemolytic Anemia (breakdown of red blood cells):</b> weakness, looking pale, feeling tired		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting ([canada.ca/drug-device-reporting](https://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

Do not use GILENYA after the expiry date shown on the box.

Store at 15-25°C.

Store in the original package, protect from moisture.

Keep out of reach and sight of children.

#### If you want more information about GILENYA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.novartis.ca](http://www.novartis.ca); or by calling 1-800-363-8883.

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