

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrGILENYA®

Fingolimod capsules

Read this carefully before you start taking **GILENYA®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **GILENYA**.

What is GILENYA used for?

GILENYA is used to treat:

- Adult patients with the relapsing and remitting form of multiple sclerosis (MS). GILENYA is generally recommended for MS patients who have not responded well to, or cannot tolerate one or more of the other therapies for multiple sclerosis.
- Children and adolescent patients (10 years to <18 years of age) with the relapsing form of MS.

How does GILENYA work?

GILENYA does not cure MS, but it helps to reduce the number of attacks (relapses) that occur, reduce inflammation in the brain (brain lesions seen on MRI scans), and slow the progression of the physical problems that happen due to MS (disability progression).

GILENYA changes how the body's immune system works by decreasing the ability of lymphocytes, a type of white blood cell, to move freely within the body. This lowers the number of lymphocytes in the blood and prevents them from reaching the brain and spinal cord. This may reduce the inflammation and nerve damage that happens in MS.

What are the ingredients in GILENYA?

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 & 0.5 mg

Do not use GILENYA if:

- you are allergic (hypersensitive) to fingolimod or to any of the other ingredients in GILENYA (see **What are the ingredients in GILENYA?**).
- your immune system is weakened (immunocompromised) due to disease (immunodeficiency syndrome) or medicines or treatments that suppress the immune system, such as medicines used to treat cancer or bone marrow transplantation.

- you have a severe active infection or an active chronic infection such as hepatitis or tuberculosis (TB).
- you have an active cancer (except for a type of skin cancer called basal cell carcinoma).
- you have severe liver disease.
- you have had a heart attack, angina (chest pain), stroke or warning of a stroke, or certain types of heart failure in the last 6 months.
- you have certain types of irregular or abnormal heartbeat (arrhythmia), or your electrocardiogram (ECG) shows prolonged QT interval before starting GILENYA.
- you are taking or have recently taken medicine for irregular heartbeat such as quinidine, disopyramide, amiodarone or sotalol (due to a possible added effect on irregular heartbeat).
- you are pregnant, think you might be pregnant or plan to get pregnant.
- you are of childbearing age and are not using effective methods of birth control.
- you are of childbearing age, until it is confirmed with a pregnancy test that you are not pregnant. This is done just before you begin treatment with 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 heart problems, such as high blood pressure, or severe untreated sleep apnea.
- you have a slow heart rate, you are already taking other medicines that slow your heart rate or you have a history of sudden loss of consciousness (fainting).
- you have a weakened immune system (due to a disease or medicines that suppress the immune system).
- you have been vaccinated within 1 month before you start taking GILENYA or you plan to receive a vaccine. You should not receive certain types of vaccines (called “live attenuated vaccines”) during and for up to 2 months after treatment with GILENYA.
- your child (10 years to <18 years of age) has not completed their vaccination schedule. They need to have completed this before starting treatment with GILENYA.
- you have never had chickenpox or have not been vaccinated for chickenpox.
- you have had infections such as hepatitis or tuberculosis (TB).
- you have or have had visual disturbances or other signs of swelling in the central vision area at the back of the eye (a condition known as macular edema), inflammation or infection of the eye (uveitis).
- you have diabetes.
- you have liver problems.
- you have low or high blood pressure.
- you have high cholesterol or triglyceride levels.
- you have kidney problems.
- you have breathing problems.
- you are breast feeding.
- you are 65 years of age or older. You may have a higher risk of side effects.

Other warnings you should know about:

Chickenpox: Patients who have not had chickenpox or have not had the chickenpox vaccine are at risk of having a serious and life-threatening chickenpox infection during treatment with GILENYA. There have been very rare fatal cases of chickenpox infection reported in patients treated with GILENYA, who also received a relatively long course of corticosteroid therapy. If you are not protected against chickenpox, your healthcare professional may recommend that you receive the chickenpox vaccine 1 month before starting treatment with GILENYA.

Human Papilloma Virus (HPV): Your healthcare professional will tell you if you need to have a vaccination against Human Papilloma Virus (HPV) before starting treatment. If you are a female, your healthcare professional will recommend HPV screening. HPV infection, including papilloma (finger-like growths on the skin and mucous membranes), dysplasia (abnormal cells on the cervix found by PAP smear in women), warts and HPV-related cancer, has been reported in patients treated with GILENYA.

Blood Tests and Monitoring: Before you start taking GILENYA and periodically during treatment, your healthcare professional will do tests to help monitor for side-effects. These will include: blood tests (to check your white blood cell counts and the health of your liver, see **Liver Problems** below), eye exams (to monitor for macular edema, see **Eye Problems** below), checks of your heart rhythm and blood pressure, and possibly lung function.

Because fingolimod has side effects on the heart (see **Heart Problems** below), you will be required to have an electrocardiogram (ECG) to check the health of your heart before you start fingolimod (or after taking the first dose of 0.5 mg when your child switches from the 0.25 mg capsule daily dose). Your healthcare professional will ask you to stay in the clinic or office for at least 6 hours after taking the first dose of fingolimod so your heart rate and blood pressure can be checked each hour and appropriate measures can be taken if heart-related side effects occur at the start of treatment. A second ECG will be done 6 hours after taking the first dose. Depending on the results of the ECG, blood pressure checks and how you are feeling, you may need to be observed for longer, possibly overnight, in a healthcare facility. The same observation process may apply if you are starting treatment again after a break from fingolimod therapy.

Heart Problems: GILENYA causes the heart rate to slow down, especially during the first month of treatment. GILENYA can also cause an irregular heartbeat, especially after the first dose (or when children/adolescents switch 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. These heart rhythm disturbances may be more likely to happen in patients with risk factors, such as heart disease, or when GILENYA is taken with certain medicines. Patients aged 65 years and older are also at higher risk.

- If you have an irregular or abnormal heartbeat or a history of sudden loss of consciousness (fainting), your condition may worsen temporarily with GILENYA. This might also happen if you have a slow heart rate or if you are taking medicines which slow the heartbeat.
- If you have any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, or seizures, while you are taking GILENYA, get immediate medical help.

Liver Problems: GILENYA may cause liver damage. Your healthcare professional should do

blood tests to check your liver before you start taking GILENYA, periodically during treatment and for two months after you have stopped taking GILENYA. 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 may lower your body's ability to fight infections. This means you may get infections more easily while you are taking GILENYA, and for up to 2 months after you stop taking it. If you have an infection before you start taking GILENYA, tell your healthcare professional. Any infection that you already have may get worse. Infections could be serious and sometimes life-threatening.

- Before you start taking GILENYA, your healthcare professional will make sure you have enough white blood cells in your blood.
- While you are 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 and/or seizures (fits), tell your healthcare professional right away. These may be the symptoms of inflammation in your brain (encephalitis) or of the membranes covering your brain (meningitis) caused by a serious fungal (Cryptococcus) or viral (herpes simplex or chickenpox) infection.
- If you believe your MS is getting worse (e.g. weakness or visual changes) or if you notice any new or unusual symptoms, talk to your healthcare professional as soon as possible. These may be the symptoms of a rare brain disorder caused by infection called progressive multifocal leukoencephalopathy (PML). Your healthcare professional might do an MRI scan to check for this condition. Your healthcare professional will decide whether you need to stop taking GILENYA.
- The use of other medications and treatments that suppress or change how the immune system works is not recommended during treatment with GILENYA because they can further increase the risk of infections.

Eye Problems: A problem with your vision, called macular edema, can occur during treatment with GILENYA. Macular edema can cause some of the same vision symptoms as an MS attack (optic neuritis), but you also may not notice any symptoms. Macular edema usually starts in the first 3 to 4 months after you start taking GILENYA. Your healthcare professional will test your vision 3 to 4 months after you start taking GILENYA, or any time you notice vision changes during treatment. Your risk of macular edema may be higher if you have diabetes or have had an inflammation of your eye called uveitis. If you have or have had visual disturbances or other signs of swelling in the central vision area (macula) at the back of the eye, uveitis or diabetes, your healthcare professional should test your vision before you start taking GILENYA.

Seizures: Some patients have had seizures (fits) while taking GILENYA. It is not known whether the seizures were related to the effects of their MS, GILENYA, or to a combination of both. If you have a seizure while taking GILENYA, get immediate medical help.

Depression and Suicidal Thoughts: Patients with MS can have depression and suicidal thoughts. Patients, families and caregivers of patients being treated with GILENYA should watch for these symptoms. Tell your healthcare professional right away if any of these symptoms occur.

Cancer Risk: The effects of GILENYA on the body's immune system may increase the risk of developing lymphoma and other cancers such as skin cancer. Lymphoma and skin cancer, mostly basal cell carcinoma, have been reported in patients treated with GILENYA.

- If you already have moles or open sores before starting treatment with GILENYA, watch for changes in the size, shape or color of moles or the healing of open sores (not healing within weeks) after you start treatment. These may be signs of skin cancer that you should talk to your healthcare professional about.
- A type of skin cancer called basal cell carcinoma (BCC) and other types of skin cancer such as malignant melanoma, squamous cell carcinoma, Kaposi's sarcoma and Merkel cell carcinoma have been reported in MS patients treated with GILENYA. While you are taking GILENYA you should check your skin regularly for unusual changes. Symptoms of BCC may include skin nodules (e.g. shiny pearly nodules) and patches or open sores that do not heal within weeks. Symptoms of other skin cancers may include abnormal growth or changes of skin, such as unusual moles, that may change in color, shape or size over time. Your healthcare professional will do regular skin examinations during your treatment with GILENYA.
- Long-term exposure to the sun and a weak immune system can affect the risk of developing Merkel cell carcinoma. You should limit your exposure to the sun and UV rays by: wearing appropriate protective clothing and regularly applying sunscreen with a high degree of UV protection.

Return of MS Symptoms: After GILENYA treatment is stopped, symptoms of MS can return and may become worse compared to before or during treatment. Tell your healthcare professional if you have worsening of MS symptoms after stopping GILENYA.

Brain Lesions: A condition with unusually large brain lesions associated with MS relapse has been rarely reported in patients treated with GILENYA. This condition is called tumefactive lesions. In case of severe relapse, your healthcare professional will consider performing an MRI scan to check for this condition and will decide whether you need to stop taking GILENYA.

Blood Disorders: GILENYA may cause the following blood conditions:

- Destruction of red blood cells (autoimmune hemolytic anemia): weakness, looking pale, feeling tired
- Low levels of platelets (thrombocytopenia): 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

If these symptoms occur, tell your healthcare professional right away.

Pregnancy: Do **not** take GILENYA if you are pregnant. GILENYA can harm your unborn baby. If you are a female who could become pregnant or are a female planning to become pregnant, before you start treatment with GILENYA your healthcare professional will:

- tell you about the risk to an unborn baby.
- ask you to do a pregnancy test to make sure you are not pregnant.
- talk to you about your birth control options. You must use effective birth control while you are taking GILENYA and for two months after you stop taking it.

If you do become pregnant while taking GILENYA tell your healthcare professional right away. You and your healthcare professional will decide what is best for you and your baby. If you become pregnant while taking GILENYA, you can call the GILENYA Pregnancy Registry at 1-855-788-5333.

Breastfeeding: You should not breastfeed while you are taking GILENYA. GILENYA can pass into breast milk and there is a risk of serious side effects for your baby.

Driving and using machines: After the first dose of GILENYA, you will need to be monitored in a medical setting for at least 6 hours to have your heart rate and blood pressure checked. Your ability to drive and use machines may be affected during and potentially 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. GILENYA should not be started while you are on these medications. If you are switching to GILENYA from another MS treatment, your healthcare professional may want to wait for several months to reduce the possible added effect on the immune

system and potential for increased risk of serious infections.

- Vaccines. If you need to receive a vaccine, talk to your healthcare professional first. While you are taking GILENYA and for up to 2 months after stopping treatment some vaccines containing live virus (live attenuated vaccines) may cause the infection that the vaccination should 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. GILENYA can be taken with or without food.
- GILENYA will stay in your body for up to 2 months after you stop taking 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 < 18 years of age):

The dose depends on the body weight:

- Children and adolescents with a body weight equal to or below 40 kg: One 0.25 mg capsule per day.
- Children and adolescents with a body weight above 40 kg: One 0.5 mg capsule per day.

Once your child has reached 40 kg in weight your healthcare professional will discuss increasing their dose from 0.25 mg once a day to 0.5 mg once a day. This 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, or regional poison control centre immediately, even if there are no symptoms.

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

Missed Dose:

If you forget a dose, skip that dose and take the next dose as planned. Do not take a double dose to make up for a forgotten dose.

If you missed a dose on one day during the first 2 weeks, or if you stop taking GILENYA for more than 7 days during weeks 3 and 4 of treatment, tell your healthcare professional right

away. Your healthcare professional may decide to monitor you at the time you take the next dose.

If you start GILENYA again after stopping for 2 weeks or more, you will need to start taking GILENYA again in a medical setting. Do not restart GILENYA after stopping it for more than two weeks without talking to your healthcare professional.

What are 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			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Bronchitis: cough with phlegm, chest pain, fever		✓	
Gastroenteritis: vomiting, nausea, diarrhea, fever		✓	
Shingles (herpes zoster infection): 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		✓	
Bradycardia (slow heartbeat): feeling dizzy, tired, awareness of own heartbeat, low blood pressure (dizziness, fainting, light-headedness, especially when you got from lying or sitting to standing)		✓	
Skin Cancer: 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		✓	
Low Levels of White blood cells: symptoms of infection (fever, sore throat, mouth ulcers, flu-like feeling)		✓	
UNCOMMON			
Pneumonia: fever, cough, difficulty breathing		✓	
Macular Edema: shadows or blind spot in the center of the vision, blurred vision, problems seeing colors or fine details		✓	
Liver Problems: nausea, vomiting, loss of appetite,		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
swelling and/or pain in the abdomen, feeling tired, itching, yellowing of the skin or eyes, dark urine			
Shortness of breath		✓	
Seizures (fits) (more frequent in children and adolescents than in adults)			✓
Thrombocytopenia (low levels of platelets): 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		✓	
RARE			
Stroke: weakness and/or loss of feeling of limbs or face, difficulty speaking, clumsiness, vision loss			✓
Peripheral Artery Disease (poor circulation in the limbs): cold, painful, discolored limb, fingers or toes			✓
Posterior Reversible Encephalopathy Syndrome (PRES): sudden severe headache, nausea, vomiting, confusion, drowsiness, personality change, paralysis, abnormal speech, seizures (fits), vision changes			✓
Lymphoma (cancer of the lymphatic system): painless swelling of lymph node, swollen tonsils, fever, chills, night sweats, feeling tired, itching,		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
unexplained weight loss, loss of appetite, persistent coughing/ difficulty breathing or not being able to breathe, headache			
VERY RARE			
Heart Problems: dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, seizures (fits)			✓
FREQUENCY NOT KNOWN			
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): headache with a stiff neck, sensitivity to light, nausea, confusion, seizures (fits)		✓	
Progressive Multifocal Leukoencephalopathy (PML) (a rare brain infection): weakness on one side of your body, problems thinking, vision changes		✓	
Human Papilloma Virus (HPV) Infection: papilloma (finger-like growths on the skin and mucous membranes), dysplasia (abnormal cells on the cervix found by PAP smear in women), warts, can lead to HPV-related cancer		✓	
Allergic Reactions: rash or itchy hives, swelling of lips, tongue or face, difficulty swallowing or breathing			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Autoimmune Hemolytic Anemia (destruction of red blood cells): 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health 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 this Patient Medication Information by visiting the Health Canada 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, or by calling 1-800-363-8883.

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