

GILENYA®

Fingolimod hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GILENYA.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.medsafe.govt.nz.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will provide.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What GILENYA is used for

GILENYA is a medicine used to treat relapsing multiple sclerosis (MS).

GILENYA does not cure MS, but it helps to reduce the number of relapses that occur and to slow the build-up of physical problems due to MS (disability progression).

GILENYA 0.5 mg hard capsules contain the active substance fingolimod, which belongs to a

group of medicine known as sphingosine-1-phosphate (S1-P) receptor modulators.

Multiple sclerosis (MS) is a long-term condition that affects the central nervous system (CNS), particularly how the brain and spinal cord work. In MS inflammation destroys the protective sheath (called myelin) around the nerves in the CNS and stops the nerves from working properly. This process is called demyelination.

The exact cause of MS is unknown. An abnormal response by the body's immune system is thought to play an important part in the process which damages the CNS.

People with MS experience repeated bouts of nervous system symptoms that reflect inflammation within the CNS. These bouts are typically called attacks or relapses. Symptoms vary from patient to patient but typically involve walking difficulties, numbness, vision problems, and problems with balance. The symptoms of a relapse may disappear completely but in some cases remain, at least partially, after the relapse is over. This form of disease is called relapsing MS or relapsing-remitting MS.

In some cases people with relapsing MS find that their symptoms gradually increase between relapses, indicating transition to another form of MS (secondary progressive MS).

GILENYA can alter the way the body's immune system works, and help to fight against attacks of the immune system by affecting the ability of some white blood cells to move freely within the body and by stopping the cells that cause inflammation from reaching the brain. This reduces nerve damage caused by MS. GILENYA may also

have a direct and beneficial effect on certain brain cells (neural cells) involved in repairing or slowing down the damage caused by MS.

In clinical studies GILENYA has been shown to cut down the number of attacks (by slightly more than half) and as a consequence, reduces the number of severe relapses and relapses that must be treated in hospital, prolongs the time without relapses and slows the progression of disability (by about a third).

Ask your doctor if you have any questions about how GILENYA works or why this medicine has been prescribed for you.

This medicine is only available with a doctor's prescription. It is not addictive.

Talk to your doctor if you have any concerns.

There is not enough information to recommend this medicine for children and adolescents under 18 years old. Experience with GILENYA in older people (more than 65 years old) is limited.

Before you take GILENYA

When you must not take it

Do not take GILENYA if you have an allergy to:

- fingolimod (the active ingredient) or to any of the other ingredients listed at the end of this leaflet.
- any other similar medicines (such as medicines of the same class or with a similar structure).

Some of the symptoms of an allergic reaction may include:

- shortness of breath;
- wheezing or difficulty breathing;

- swelling of the face, lips, tongue or other parts of the body;
- rash, itching or hives on the skin.

Do not take GILENYA if you have any of the following medical conditions:

- if, in the last 6 months, you have had a heart attack, angina, stroke or warning of a stroke or certain types of heart failure.
- if you have certain types of irregular or abnormal heartbeat (arrhythmia), or your electrocardiogram (ECG) shows prolonged QT interval before starting Gilenya.
- if 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).

If you are not sure whether any of the above medical conditions apply to you, check with your doctor.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

You should avoid becoming pregnant while taking GILENYA or in the two months after you stop taking it because of the risks of harming an unborn child.

Therefore, if you are a female who could become pregnant, before you start treatment with Gilenya your doctor:

- will tell you about the risk to an unborn baby,

- will ask you to do a pregnancy test in order to ensure that you are not pregnant,

and

- you should use effective contraception while taking Gilenya and for two months after you stop taking it.

Talk with your doctor about reliable methods of birth control that you should use during treatment and for 2 months after you stop treatment.

If you do become pregnant while taking GILENYA tell your doctor right away.

You and your doctor will decide what is best for you and your baby.

You should not breast-feed while you are taking GILENYA. GILENYA can pass into breast milk and there is a risk of serious side effects for a breast-fed baby.

Talk with your doctor before breast-feeding while you take GILENYA.

Checking the health of your heart is important if any of the following applies to you. Your doctor may decide not to use GILENYA. If your doctor thinks that GILENYA is good for you, he/she may refer you first to a cardiologist (doctor specialised in heart disease). You may also be monitored overnight by a health care professional after taking the first dose of GILENYA.

Tell your doctor before taking GILENYA:

- if you have, uncontrolled high blood pressure if when you sleep you are severely affected by interruptions of breathing (sleep apnea that is not treated). Your doctor may decide not to use GILENYA if you have or have had one of these conditions.
- if you suffer from a slow heart rate or if you have a history of sudden loss of consciousness (fainting). Your doctor may decide not to use GILENYA, or may refer you first to a cardiologist to switch to medicines that do not slow your heart rate, or to decide how you

should be observed after you take the first dose of GILENYA.

- if you have no history of chickenpox or have not been vaccinated against varicella zoster virus. Your doctor will test your status of the antibody against this virus and may decide to vaccinate you if you do not have antibodies to this virus. In this case, you will start GILENYA treatment one month after the full course of the vaccination is completed.
- Your doctor will consider whether you need to have a vaccination against Human Papilloma Virus (HPV) before starting treatment. If you are a female, your doctor will also recommend HPV screening. HPV infection, including papilloma, dysplasia, warts and HPV-related cancer, has been reported in patients treated with Gilenya.

Also tell your doctor if you have any of the following medical conditions:

- if you have a lowered immune response (due to a disease or medicines that suppress the immune system, see “*Taking other medicines*”). You may get infections more easily or an infection you already have may get worse.
- if you have an infection. Your doctor will confirm whether you have enough white blood cells in your blood to start this medicine.
- problems with your liver. You will have a blood test to check your liver function before and during treatment with GILENYA and until two months after stopping treatment. If liver problems are detected your doctor may decide to discontinue treatment.
- if 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 oedema, see below), inflammation or infection of the

eye (uveitis) or if you have diabetes. Your doctor may want you to undergo an eye examination before you start GILENYA and at regular intervals after the start of GILENYA treatment.

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Alcohol, diet, exercise and your general health all strongly affect the control of your diabetes.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with GILENYA. These include:

- Medicines for an irregular heartbeat such as, quinidine, procainamide, amiodarone or sotalol (see “Do not take Gilenya”).
- Medicines that suppress or modulate the immune system, including other medicines used to treat MS such as:
 - beta-interferon
 - glatiramer acetate
 - natalizumab
 - mitoxantrone
 - dimethyl fumarate
 - terifluomide
 - alemtuzumab
 - or corticosteroidsdue to a possible added effect on the immune system.
- Medicines that slow down heartbeat such as:
 - atenolol (called beta-blocker)
 - verapamil ordiltiazem (called calcium channel blockers)
 - digoxin, ivabradine or others.

Your doctor may decide not to use GILENYA or may refer you first to a cardiologist to switch to medicines that do not slow your heart rate or to decide how you should be observed after the first dose of GILENYA.

- Vaccines, as during and up to 2 months after treatment with GILENYA, administration of some vaccines, containing live virus (called live attenuated vaccines), may result in an infection that the vaccination should prevent, while others may not work well.

You may need to take different amounts of your medicines or to take different medicines while you are taking GILENYA. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take GILENYA

Always take GILENYA exactly as your doctor or pharmacist has told you.

Their directions may differ from the information contained in this leaflet.

Do not exceed the recommended dose.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The usual dose is one capsule per day (0.5 mg of fingolimod).

How to take it

Swallow GILENYA capsules whole with a glass of water.

GILENYA can be taken with or without food.

First dose precaution

Before you take the first dose of GILENYA, your doctor will do an ECG to check your heart rate and rhythm.

You will need to stay at the doctor’s office or clinic for 6 hours after taking the first dose of GILENYA so that your heart rate and blood pressure can be checked each hour by a health care professional. At the end of the 6-hour observation period, you will be required to have a second ECG. In case of abnormal ECG recording or slow heart rate at the end of the 6-hour observation period, you may be observed for longer and overnight if necessary, by a health care professional. The same recommendation may apply if you start treatment again after a break from GILENYA therapy, depending on how long the break is and how long you have been receiving treatment. At the beginning of treatment, GILENYA can cause the heart rate to slow down. GILENYA can also cause an irregular heartbeat, especially after the first dose. Irregular heartbeat usually returns to normal in less than one day. Slow heart rate usually returns to normal within one month.

Tell your doctor if you feel dizzy or tired, or are conscious of your heartbeat.

If your heart rate slows down after your first dose, you may feel dizzy or tired, or may be consciously aware of your heartbeat. If your heart rate slows down too much or your blood pressure drops, you may need treatment right away. In this case you will be monitored overnight by a health care professional and the same observation process that took place for your first dose of GILENYA will also apply for your second dose.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

Do not stop taking GILENYA unless your doctor tells you to.

If GILENYA treatment is stopped, symptoms of MS can return and may become worse compared to before or during treatment. Tell your doctor if you have worsening of MS symptoms after stopping GILENYA.

GILENYA will stay in your body for up to 2 months after you stop taking it. Your white blood cell count (lymphocyte count) may also remain low during this time and the side effects described in this leaflet may still occur.

If you stop taking GILENYA:

- for one day or more during the first 2 weeks treatment, or
- for more than 7 days during weeks 3 and 4 of treatment, or
- for more than 2 weeks after your first month of GILENYA treatment,

the initial effect on your heart rate may occur again.

If you restart GILENYA treatment, your doctor may decide to monitor your heart rate and blood pressure every hour, to run ECGs or to keep you under monitoring overnight.

If you are a woman, see section *Things you must do*.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have missed a dose on one day during the first 2 weeks, contact your doctor right away.

Your doctor may decide to observe you at the time you take the next dose.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose) or if you have taken a first dose by mistake

Immediately telephone your doctor or Poisons Information Centre (telephone number: 13 11 26), or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have accidentally taken too much GILENYA or taken a first dose of GILENYA by mistake.

Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

You may need urgent medical attention. Your doctor may decide to observe you with heart rate and blood pressure measurements every hour, run ECGs and he may decide to monitor you overnight.

Symptoms of an overdose may include:

- Swelling in hands or feet
- Tingling or numbness in hands or feet
- Muscle pain
- Fever.

While you are taking GILENYA

Things you must do

You should avoid becoming pregnant while taking GILENYA or in the two months after you stop taking it because GILENYA may harm your unborn baby.

Talk to your doctor about the associated risk.

Talk with your doctor about reliable methods of birth control that you should use during treatment and for 2 months after you stop treatment.

If you become pregnant while taking this medicine, tell your doctor immediately.

GILENYA should not be taken if you are pregnant.

A type of skin cancer called basal cell carcinoma (BCC) and other skin tumours such as malignant melanoma, squamous cell carcinoma, Kaposi's sarcoma and Merkel cell carcinoma have been reported in MS patients treated with Gilenya. Your doctor will carry out regular skin examinations during your treatment with Gilenya. Talk to your doctor straight away if you notice any of the following symptoms or diseases:

- symptoms of BCC may include skin nodules (e.g. shiny pearly nodules), patches or open sores that do not heal within weeks.

- symptoms of other skin tumours may include abnormal growth or changes of skin tissue (e.g. unusual moles) which may present as a change in color, shape or size over time.

- 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.

A type of cancer of the lymphatic system (lymphoma) has been reported in MS patients treated with Gilenya.

Tell your doctor about any changes in your vision, particularly if:

- the centre of your vision becomes blurred or has shadows
- if you develop a blind spot in the centre of your vision

- if you have problems seeing colours or fine detail.

GILENYA may cause macula oedema (swelling of a small area at the back of the eye), which usually happens during the first 4 months of treatment. Your chance of developing macular oedema is higher if you have diabetes or have had an inflammation of the eye called uveitis. It can cause some of the same vision symptoms as an MS attack (optic neuritis).

Tell your doctor if you think you have an infection, have a fever, or feel like you have the flu during your treatment with GILENYA.

GILENYA lowers the white blood cell count (particularly the lymphocyte count). White blood cells fight infection. While you are taking GILENYA (and for up to 2 months after you stop taking it), you may get infections more easily. Any infection that you already have may get worse. Infections can be serious and sometimes life-threatening.

Tell your doctor as soon as possible if you notice any of the following symptoms while you are taking GILENYA because it could be serious:

- signs that your MS is getting worse (e.g. weakness or visual change) or if you notice any new or unusual symptoms (e.g. changes in thinking or memory leading to confusion and changes to your personality). These may be the symptoms of a rare brain disorder caused by infection and called progressive multifocal leukoencephalopathy (PML) or a condition called tumefactive lesions. Your doctor may organise an MRI scan to help decide if you need to stop taking Gilenya. If PML is confirmed, your doctor will stop treatment with Gilenya. Some people with PML may have a reaction as Gilenya is removed from the body. This reaction (known as immune reconstitution inflammatory syndrome or IRIS)

may lead to your condition getting worse, including worsening of the symptoms described above.

- If you think you have an infection; a fever; feel like you have the flu, or have a headache accompanied by stiff neck, sensitivity to light, nausea, and/or confusion, or seizures/fits (these may be symptoms of meningitis and/or encephalitis)
- yellowing of your skin or the whites of your eyes, abnormally dark urine or unexplained nausea, vomiting and tiredness. These may be signs of liver injury.
- sudden onset of severe headache, confusion, seizures and vision changes Which are symptoms of a condition called posterior reversible encephalopathy syndrome (PRES)(has been rarely reported in MS patients treated with Gilenya).

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do regular checks to help prevent you from having side effects from the medicine. This includes blood tests to check your liver function and regular skin checks.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking GILENYA.

Tell any other doctor, dentist or pharmacist who treats you that you are taking GILENYA.

Things you must not do

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Your doctor will tell you whether your illness allows you to drive vehicles and use machines safely.

GILENYA is not expected to affect your ability to drive and use machines.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking GILENYA even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by these lists of possible side effects. You may not experience any of them.

Ask your doctor, pharmacist or diabetes educator to answer any questions you may have.

Tell your doctor if you notice any of the following symptoms and they worry you:

- flu symptoms such as tiredness, chills, sore throat, joint or muscles aching, fever
- Feeling of pressure or pain in the cheeks and forehead (sinusitis)
- Headache
- Diarrhoea
- Back pain
- Cough.

The above side effects are very common and non-serious. If any of these affects you severely, tell your doctor.

Tell your doctor if you notice any of the following symptoms and they affect you severely:

- ringworm, a fungal infection with ring-like red itchy rash
- Dizziness
- Tingling or numbness
- Severe headache often accompanied by nausea, vomiting and sensitivity to light (signs of migraine)
- Weakness
- Itchy, red, burning rash (signs of eczema)

- Hair loss
- Itching
- Weight loss
- Breathlessness
- Depression
- Eye pain.

The above side effects are common and non-serious. If any of these affects you severely, tell your doctor.

The following side effects have also been reported:

- nausea
- muscle pain
- joint pain
- weight loss.

Tell your doctor straight away if you notice any of the following:

- bronchitis with symptoms such as cough with phlegm, chest pain, fever
- gastroenteritis with symptoms such as vomiting, nausea, diarrhoea, fever
- shingles or herpes zoster symptoms such as blisters, burning, itching or pain around the mouth or genitals. Other symptoms may be fever and weakness in the early stages of infection, followed by numbness, itching, and red patches or blisters on the face or trunk, with severe pain
- fever, cough, difficulty breathing, tiredness, aching joints and muscles which are signs of infections. While you are taking GILENYA (and for up to 2 months after you stop taking it), you may get infections more easily. Any infection that you already have may get worse. Infections could be serious and life-threatening
- slow heartbeat (bradycardia)
- serious irregularity in heart beat after first dose that is temporary and that returns to normal during the 6-hour observation period
- pneumonia with symptoms such as fever, cough, difficulty breathing
- symptoms such as shadows or blind spot in the centre of the vision, blurred vision, problems

seeing colours or details which are symptoms of macular oedema (swelling in the central vision area of the retina at the back of the eye).

- moles which may change size, shape, elevation or colour over time, or new moles. These may be symptoms of melanoma, a type of skin cancer usually developing from an unusual mole (naevus). The moles may itch, bleed or ulcerate.
- pearly nodule, patches or open sores that do not heal within weeks, which could be a type of skin cancer called basal cell carcinoma (BCC)
- hard red bump, a sore with a scab or crust, or a new sore on a scar you already had which could be a type of skin cancer called squamous cell carcinoma.
- skin-colored or bluish-red, painless bumps, often on the face, head or neck or hard painless lumps which could be a type of skin cancer called Merkel cell carcinoma. Long-term exposure to the sun and a weak immune system can affect the risk of developing Merkel cell carcinoma.
- skin lesions of unusual colour
- Human Papilloma Virus (HPV) infection, including papilloma, dysplasia, warts and HPV-related cancer.
- yellow skin or eyes, light-coloured or abnormally dark urine, unexplained nausea, vomiting, abdominal pain, tiredness or loss of appetite. Your doctor may carry out blood tests to check your liver function and may consider stopping GILENYA treatment if your liver problem is serious.
- worsening of MS symptoms (for example changes in mood or behavior, new or worsening weakness on one side of the body, changes in vision, confusion, memory lapses or speech and communication

difficulties) which could be signs of a rare brain disorder caused by infection called progressive multifocal leukoencephalopathy.

These side effects can be serious.

Tell your doctor immediately or go to Accident and Emergency if you notice any of the following:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- sudden onset of rash or hives
- sudden onset of severe headache, confusion, seizures and vision changes, which may be symptoms of a rarely reported condition called posterior reversible encephalopathy syndrome (PRES).
- an infection, fever, feel like you have the flu, or have a headache accompanied by stiff neck, sensitivity to light, nausea, and/or confusion which are symptoms of cryptococcal infection (a type of fungal infection), including Cryptococcal meningitis, and meningitis/ encephalitis (caused by herpes or varicella zoster virus).
- convulsions, fits.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects can only be found when your doctor does tests to check your progress. These include:

- hypertension (Gilenya may cause a mild increase in blood pressure)
- higher levels of liver enzymes and/or liver injury
- increased level of blood fat (triglycerides)
- changes to blood cell counts
- abnormal lung function test results starting after one month of treatment, remaining stable after that and reversible after treatment discontinuation.

After using GILENYA

Tell your doctor straight away, if you believe your MS is getting worse after you have stopped treatment with GILENYA, because it could be serious.

Symptoms of MS can return and may become worse compared to before or during treatment.

Storage

- Keep your medicine in the original container until it is time to take it.
- Store it in a cool dry place where the temperature stays below 30°C.
- Do not store GILENYA or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any capsules you have left over.

Product description

What it looks like

GILENYA 0.5 mg capsules are white opaque body and bright yellow opaque cap; radial imprint with black ink, “FTY 0.5 mg” on cap and two radial bands imprinted on the body with yellow ink, containing white to almost white powder.

GILENYA capsules are available in boxes containing 7, 28 or 84 capsules. Not all presentations might be marketed.

Ingredients

Each GILENYA capsule contains 0.56 mg of fingolimod hydrochloride (equivalent to 0.5 mg of fingolimod) as the active ingredient. It also contains the following inactive ingredients:

- Mannitol
- Magnesium stearate
- Titanium dioxide
- Gelatin

GILENYA does not contain gluten, tartrazine or any other azo dyes.

Sponsor

GILENYA is supplied in New Zealand by:

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Telephone 0800 354 335

® = Registered Trademark

This leaflet was prepared in May 2026.

Internal Document Code:

CMI (gil210526cNZ) based on DS (gil210526iNZ)