

# GILENYA<sup>®</sup>

*Fingolimod hydrochloride*

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## Consumer Medicine Information

### **What is in this leaflet**

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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.novartis.com.au](http://www.novartis.com.au) for Australia or [www.medsafe.govt.nz](http://www.medsafe.govt.nz) for New Zealand.**

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**

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Gilenya treats 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 can alter the way the body's immune system works and is used to treat relapsing multiple sclerosis.

Gilenya is a new type of medicine known as sphingosine-1-phosphate (S1-P) receptor modulators. The active substance of Gilenya is fingolimod.

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

MS is characterised by 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 imbalance. 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 helps 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 of 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.

There is not enough information to recommend this medicine for children.

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### **Before you take GILENYA**

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#### ***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, if listed in the PI)

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 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***

**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.** 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.

**Tell your doctor if you have any of the following medical conditions:**

- if you have a slow resting heart rate (less than 55 beats per minute), if you are taking medicines that slow your heart rate, if you have irregular or abnormal heartbeat or a history of sudden loss of consciousness. Your doctor may check your heart rate before you take the first dose of Gilenya (or if you are resuming treatment after a break of more than 2 weeks).

- if you have a lowered immune response (due to a disease or medicines that suppress the immune system). You may get infections more easily or an infection you already have may get worse.
- problems with your liver.
- 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.

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.

- Medicines for irregular heartbeat such as, quinidine, procainamide, amiodarone or sotalol. Your doctor may decide not to use Gilenya if you take these medicines due to a possible added effect on irregular heartbeat.

- Medicines that suppress or modulate the immune system including other medicines used to treat MS such as beta-interferon, glatiramer acetate, natalizumab or mitoxantrone due to a possible added effect on the immune system.
- Medicines that slow down heartbeat (called beta-blockers) such as atenolol due to a possible added effect on heartbeat on the first days you start Gilenya.
- Vaccines. During and for up to 2 months after treatment with Gilenya, administration of some vaccines containing live virus may result in infection that the vaccination should prevent, while others may not work well.

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## **How to take GILENYA**

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**Follow all directions given to you by your doctor and pharmacist carefully.**

They may differ from the information contained in this leaflet.

**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 tablets 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 may 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 can be checked. At the beginning of treatment, Gilenya causes 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.**

### ***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.**

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 have to restart Gilenya more than 2 weeks after you stopped taking it, the initial effect on your heart rate may occur again. It is recommended that you be observed for 6 hours after taking the first dose of Gilenya so that your heart rate can be checked.

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.**

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)***

**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. 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.

Symptoms of an overdose may include:

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

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## **While you are taking GILENYA**

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### ***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.

**Tell your doctor about any changes in your vision, especially if:**

- the centre of your vision gets blurry 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 in 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 fever, or feel like you have the flu.**

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 could be serious and life-threatening.

**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.

**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 have an influence on your ability to drive and use machines.

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## **Side effects**

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**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 side effects and they worry you:**

- Bronchitis with symptoms such as cough with phlegm, chest pain, fever
- Gastroenteritis with symptoms such as vomiting, nausea, diarrhoea, fever
- Infection from herpes virus (shingles or herpes zoster) with symptoms such as blisters,

burning, itching or pain around the mouth or genitals. Other symptoms may be fever 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)

The above side effects are common and can be serious.

- Pneumonia with symptoms such as fever, cough, difficulty breathing
- Symptoms such as shadows or blind spot in the center 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).

The above side effects are uncommon, can be serious.

- Infection from flu virus with symptoms such as tiredness, chills, sore throat, joint or muscles aching, fever
- Headache
- Diarrhoea
- Back pain
- Cough

The above side effects are very common and non-serious.

- Feeling of pressure or pain in the cheeks and forehead (sinusitis)
- Infection from fungi affecting the skin, hair or nails (ringworm)
- 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
- Blurred vision
- Hypertension. Gilenya may cause a mild increase in blood pressure

The above side effects are common and non-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
- yellow skin or eyes, light-coloured or darkening of the urine, unexplained nausea, vomiting, abdominal pain, tiredness or loss of appetite. Your doctor may request blood tests to check and to monitor your liver function and may consider stopping treatment if your liver problem is serious.

**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.

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## **After using GILENYA**

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### ***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 tablets you have left over.**

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**Product description**

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***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 tablets are available in boxes containing 7, 28 or 84 tablets.

***Ingredients***

Each GILENYA tablets contains 50 mg of vildagliptin 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 Australia by:

NOVARTIS Pharmaceuticals  
Australia Pty Limited  
ABN 18 004 244 160

54 Waterloo Road  
North Ryde NSW 2113

Telephone: 1 800 671 203

Web site: [www.novartis.com.au](http://www.novartis.com.au)

GILENYA is supplied in New Zealand by:

Novartis New Zealand Limited  
Private Bag 65904  
Mairangi Bay  
Auckland  
Building G, 5 Orbit Drive  
Rosedale  
Auckland 0632

Telephone 0800 652 422

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