

GILENYA[®] HARD CAPSULES

Fingolimod 0.25 mg & 0.5 mg

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What Gilenya is used for

Gilenya is a prescription medicine taken orally, and is used in adults, children and adolescents (10 years of age and above) to treat relapsing forms of 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).

How Gilenya works

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 in adults and by slightly more than three quarters in children/adolescents) and as a consequence, to reduce the number of severe relapses and relapses that must be treated in hospital, to prolong the time without relapses and to slow the progression of disability (by about a third in adults and by about three quarters in children/adolescents).

If you have any questions about how Gilenya works or why this medicine has been prescribed for you or your child, ask your doctor.

Before you use Gilenya

- When you must not use it

Do not take Gilenya if you:

- have had a heart attack, unstable angina, stroke or mini-stroke (transient ischemic attack or TIA) or certain types of heart failure in the last 6 months
- have certain types of irregular or abnormal heartbeat (arrhythmia), including patients in whom a heart finding called prolonged QT is seen on ECG before starting Gilenya
- have a heart rhythm problem that needs treatment with certain medicines
- pregnant or a woman of childbearing potential not using effective contraception
- are allergic to fingolimod or any of the ingredients of Gilenya listed. See the end of this leaflet for a complete list of ingredients in Gilenya. Symptoms of an allergic reaction may include: rash, itchy hives, or swelling of the lips, tongue or face.

Talk to your doctor before taking Gilenya if you have any of these conditions or do not know if you have any of these conditions.

- Before you start using it

Before you take Gilenya, tell your doctor about all your medical conditions, including if you had or now have:

- an irregular or abnormal heartbeat (arrhythmia)
- a history of stroke or mini-stroke
- heart problems, including heart attack or angina
- a history of repeated fainting (syncope)
- a fever or infection, or you are unable to fight infections due to a disease or have taken medicines that lower your immune system.
- recently received a vaccine or are scheduled to receive a vaccine
- chickenpox or have received the vaccine for chickenpox. Your doctor

may do a blood test for chickenpox virus. You may need to get the full course of the vaccine for chickenpox and then wait 1 month before you start taking Gilenya. your child has completed their vaccination schedule.

- your child needs to have completed their vaccination schedule before starting treatment with Gilenya.
- eye problems, especially an inflammation of the eye called uveitis.
- diabetes
- breathing problems, including during your sleep
- liver problems
- high blood pressure
- types of skin cancer called basal cell carcinoma (BCC) or melanoma.
- are pregnant or plan to become pregnant. Gilenya may harm your unborn baby. Talk to your doctor if you are pregnant or are planning to become pregnant. Tell your doctor right away if you become pregnant while taking Gilenya or if you become pregnant within 2 months after you stop taking Gilenya.
 - You should stop taking Gilenya 2 months before trying to become pregnant.
 - If you are a female who can become pregnant, you should use effective birth control during your treatment with Gilenya and for at least 2 months after you stop taking Gilenya.
- are breastfeeding or plan to breastfeed. It is known if GILENYA passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take GILENYA.

- Taking other medicines

Tell your doctor about all the medicines you take or have recently taken, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your doctor if you take medicines that affect your immune

system, including corticosteroids, or have taken them in the past.

Know the medicines you take. Keep a list of medicines with you to show your doctor and pharmacist when you get a new medicine.

Using Gilenya and other medicines together may affect each other causing serious side effects.

How to use Gilenya

Adults and children will be observed by a healthcare professional for at least 6 hours after taking their first dose of Gilenya. Children should also be observed by a healthcare professional for at least 6 hours after taking their first dose of 0.5 mg of Gilenya when switching from the 0.25 mg dose. See “What is the most important information I should know about Gilenya?”

- How much to use

Take Gilenya exactly as your doctor tells you to take it.

Take Gilenya 1 time each day.

Swallow whole Gilenya capsules, without opening them.

Take Gilenya with or without food.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Do not stop taking Gilenya without talking with your doctor first.

- If you forget to use it

Call your doctor right away if you miss a dose of Gilenya. You may need to be observed by a healthcare professional for at least 6 hours when you take your next dose. If you need to be observed by a healthcare professional when you take your next dose of Gilenya you will have:

- an ECG before you take your dose
- hourly pulse and blood pressure measurements after you take the dose
- an ECG 6 hours after your dose

- If you use too much (overdose)

If you take too much Gilenya, call your doctor or go to the nearest hospital emergency room right away.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Gilenya.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Gilenya to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

What is the most important information I should know about Gilenya?

Gilenya can cause serious side effects, including:

- Slow heart rate (bradycardia or bradyarrhythmia) when you start taking Gilenya. Gilenya can cause your heart rate to slow down, especially after you take your first dose. You will have a test, called an electrocardiogram (ECG), to check the electrical activity of your heart before you take your first dose of Gilenya.

All adults and children will be observed by a healthcare professional for at least 6 hours after taking their first dose of Gilenya. Children should also be observed by a healthcare professional for at least 6 hours after taking their first dose of 0.5 mg of Gilenya when switching from the 0.25 mg dose.

After you take your first dose of Gilenya, and after a child takes their first dose of 0.5 mg of Gilenya when switching from the 0.25 mg dose:

- Your pulse and blood pressure should be checked every hour.
- You should be observed by a healthcare professional to see if you have any serious side effects. If your heart rate slows down too much, you may have symptoms such as:
 - dizziness
 - tiredness
 - feeling like your heart is beating slowly or skipping beats
 - chest pain

- If you have any of the symptoms of slow heart rate, they will usually happen during the first 6 hours after your first dose of Gilenya. Symptoms can happen up to 24 hours after you take your first Gilenya dose.
- 6 hours after you take your first dose of GILENYA you will have another ECG. If your ECG shows any heart problems or if your heart rate is still too low or continues to decrease, you will continue to be observed.
- If you have any serious side effects after your first dose of Gilenya, especially those that require treatment with other medicines, you will stay in the medical facility to be observed overnight. You will also be observed for any serious side effects for at least 6 hours after you take your second dose of Gilenya the next day.
- If you have certain types of heart problems, or if you are taking certain types of medicines that can affect your heart, you will be observed overnight after you take your first dose of Gilenya.

Your slow heart rate will usually return to normal within 1 month after you start taking Gilenya. Call your doctor or go to the nearest hospital emergency room right away if you have any symptoms of a slow heart rate.

If you miss 1 or more doses of Gilenya, you may need to be observed by a healthcare professional when you take your next dose. Call your doctor if you miss a dose of Gilenya. See “If you forget to use it”.

- **Pregnancy.** Do not use Gilenya during pregnancy, if you are trying to become pregnant or if you are a woman who could become pregnant and you are not using effective contraception. If Gilenya is used during pregnancy, there is a risk of harm to the unborn baby.

- **Infections.** Gilenya can increase your risk of serious infections that can be life-threatening and cause death. You should not receive live vaccines during treatment with Gilenya and for 2 months after you stop taking Gilenya. Talk to your doctor before you receive a vaccine during treatment and for 2 months after treatment with Gilenya. If you receive a

live vaccine, you may get the infection the vaccine was meant to prevent. Vaccines may not work as well when given during treatment with Gilenya. Human Papilloma Virus (HPV). Due to risk of HPV infection please consult your doctor for routine pap-smear. Gilenya lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 2 months of stopping treatment. Your doctor may do a blood test to check your white blood cells before you start taking Gilenya. Call your doctor right away if you have any of these symptoms of an infection during treatment with Gilenya and for 2 months after your last dose of Gilenya:

- fever
- tiredness
- body aches
- chills
- nausea
- vomiting
- headache with fever, neck stiffness, sensitivity to light, nausea, or confusion (these may be symptoms of meningitis, an infection of the lining around your brain and spine)

- Progressive multifocal leukoencephalopathy (PML). PML is a rare brain infection that usually leads to death or severe disability. If PML happens, it usually happens in people with weakened immune systems but has happened in people who do not have weakened immune systems. Symptoms of PML get worse over days to weeks. Call your doctor right away if you have any new or worsening symptoms of PML, that have lasted several days, including:

- weakness on 1 side of your body
- loss of coordination in your arms and legs
- decreased strength
- problems with balance
- changes in your vision
- changes in your thinking or memory
- confusion
- changes in your personality

- A problem with your vision called macular edema. Macular edema can cause some of the same vision symptoms

as a multiple sclerosis (MS) attack (optic neuritis). You may not notice any symptoms with macular edema. If macular edema happens, it usually starts in the first 3 to 4 months after you start taking Gilenya. Your doctor should test your vision before you start taking Gilenya and 3 to 4 months after you start taking Gilenya, or any time you notice vision changes during treatment with Gilenya. Your risk of macular edema is higher if you have diabetes or have had an inflammation of your eye called uveitis.

- Call your doctor right away if you have any of the following:
 - blurriness or shadows in the center of your vision
 - a blind spot in the center of your vision
 - sensitivity to light
 - unusually colored (tinted) vision

Side effects

Gilenya can cause serious side effects, including:

- See “What is the most important information I should know about Gilenya?”
- swelling and narrowing of the blood vessels in your brain. A condition called PRES (Posterior Reversible Encephalopathy Syndrome) has happened rarely in adults taking Gilenya. Symptoms of PRES usually get better when you stop taking Gilenya. However, if left untreated, it may lead to a stroke. Call your doctor right away if you have any of the following symptoms:
 - sudden severe headache
 - sudden confusion
 - sudden loss of vision or other changes in your vision
 - seizure
- breathing problems. Some people who take Gilenya have shortness of breath. Call your doctor right away if you have new or worsening breathing problems.
- liver problems. Gilenya may cause liver problems. Your doctor should do blood tests to check your liver before you start taking Gilenya. Call your doctor 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

- severe worsening of multiple sclerosis after stopping Gilenya. When Gilenya is stopped, symptoms of MS can return and become worse compared to before or during treatment. Many people who have worsening of MS symptoms after stopping Gilenya do not return to the level of function that they had before stopping Gilenya. This worsening happens most often within 12 weeks after stopping GILENYA, but can happen later. Always talk to your doctor before you stop taking Gilenya for any reason. Tell your doctor if you have worsening symptoms of MS after stopping Gilenya.
- increased blood pressure. Your doctor should check your blood pressure during treatment with Gilenya.
- types of skin cancer called basal cell carcinoma (BCC) and melanoma. Tell your doctor if you have any changes in the appearance of your skin, including changes in a mole, a new darkened area on your skin, a sore that does not heal, or growths on your skin such as a bump that may be shiny, pearly white, skin-colored, or pink. Your doctor should check your skin for any changes during treatment with Gilenya. Limit the amount of time you spend in sunlight and ultraviolet (UV) light. Wear protective clothing and use a sunscreen with a high sun protection factor.
- allergic reactions. Call your doctor if you have symptoms of an allergic reaction, including a rash, itchy hives, or swelling of the lips, tongue or face.
- The most common side effects of Gilenya include:
 - headache
 - abnormal liver tests
 - diarrhea
 - cough
 - flu
 - inflammation of the sinuses (sinusitis)

- back pain
- stomach-area (abdominal) pain
- pain in arms or legs
- Tell your doctor if you have any side effect that bothers you or that does not go away.
- These are not all of the possible side effects of Gilenya. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Gilenya

- Storage

Do not store above 30°C, protect from moisture.

Keep Gilenya and all medicines out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Gilenya is supplied as hard capsules for oral use.

0.25 mg hard capsules have ivory opaque body and cap.

0.5 mg hard capsules have white opaque body and bright yellow opaque cap..

- Ingredients

Each hard capsule contains 0.25 mg fingolimod or 0.5 mg fingolimod.

0.25 mg capsules

- Active ingredient
Fingolimod
- Inactive ingredients
Mannitol, hydroxypropylcellulose, hydroxypropylbetadex, magnesium stearate, gelatin, titanium dioxide, yellow iron oxide.

0.5 mg capsules

- Active ingredient
Fingolimod
- Inactive ingredients
Mannitol, Magnesium stearate, Gelatin, Titanium dioxide, Yellow Iron Oxide
- MAL number:
Gilenya 0.25 mg: MAL20046075ARZ
Gilenya 0.5 mg: MAL12015017ARZ

Manufacturer

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Product Registration Holder

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