

Pr **TEVA-FINGOLIMOD**

Fingolimod Capsules

Guide for Patients and Caregivers

Read this carefully before you start taking Teva-Fingolimod 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 Teva-Fingolimod.

This material was developed by Teva Canada Limited,
as part of the risk minimization plan for Teva-Fingolimod.
This material is not intended for promotional use.

What is Teva-Fingolimod used for

Teva-Fingolimod is used to treat adult patients with the relapsing and remitting form of multiple sclerosis (MS). Teva-Fingolimod 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.

Who should not take Teva-Fingolimod

Do not use Teva-Fingolimod if:

- you are allergic (hypersensitive) to fingolimod or to any of the other ingredients listed in the Patient Medication Information leaflet.
- 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.
- 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 Teva-Fingolimod.
- 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, suspect you may be pregnant or plan to get pregnant.
- you are of childbearing age 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 Teva-Fingolimod.

What you should tell your doctor BEFORE taking Teva-Fingolimod

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Teva-Fingolimod. 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 Teva-Fingolimod 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 Teva-Fingolimod.
- 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 Teva-Fingolimod. There have been very rare fatal cases of chickenpox infection reported in patients treated with Teva-Fingolimod, 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 Teva-Fingolimod.

Human Papilloma Virus (HPV): Your healthcare professional doctor will consider whether to 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 doctor will also 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 Teva-Fingolimod.

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

Because fingolimod has side effects on the heart (see Heart Problems), 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: Teva-Fingolimod causes the heart rate to slow down, especially during the first month of treatment. Teva-Fingolimod 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. These heart rhythm disturbances may be more likely to happen in patients with

risk factors, such as heart disease, or when Teva-Fingolimod is taken with certain medicines. Patients aged 65 years and older are also at a 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 Teva-Fingolimod. 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 Teva-Fingolimod, get immediate medical help.

Liver Problems: Teva-Fingolimod may cause liver damage. Your healthcare professional should do blood tests to check your liver before you start taking Teva-Fingolimod and periodically during treatment and for two months after you have stopped taking Teva-Fingolimod. 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: Teva-Fingolimod may lower your body's ability to fight infections. This means you may get infections more easily while you are taking Teva-Fingolimod, and for up to 2 months after you stop taking it. If you have an infection before you start taking Teva-Fingolimod, 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 Teva-Fingolimod, your healthcare professional will make sure you have enough white blood cells in your blood.
- While you are taking Teva-Fingolimod, 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 membranes (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 an 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 Teva-Fingolimod.
- The use of other medications and treatments that suppress or change how the immune system works is not recommended during treatment with Teva-Fingolimod because they can further increase the risk of infections.

Eye problems: A problem with your vision, called macular edema, can occur during treatment with Teva-Fingolimod. 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 Teva-Fingolimod. Your healthcare professional will test your vision 3 to 4 months after you start taking Teva-Fingolimod, 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 Teva-Fingolimod.

Seizures: Some patients have had seizures (fits) while taking Teva-Fingolimod. It is not known whether the seizures were related to the effects of their MS, Teva-Fingolimod, or to a combination of both. If you have a seizure while taking Teva-Fingolimod, 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 Teva-Fingolimod should watch for these symptoms. Tell your healthcare professional right away if any of these symptoms occur.

Cancer Risk: The effects of Teva-Fingolimod 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 Teva-Fingolimod.

- If you already have moles or open sores before starting treatment with Teva-Fingolimod, 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 Teva-Fingolimod. While you are taking Teva-Fingolimod 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 Teva-Fingolimod.
- 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 Teva-Fingolimod 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 Teva-Fingolimod.

Brain Lesions: A condition with unusually large brain lesions associated with MS relapse has been rarely reported in patients treated with Teva-Fingolimod. 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 Teva-Fingolimod.

Blood Disorders: Teva-Fingolimod 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 contact your health care professional right away.

Pregnancy: Do **not** take Teva-Fingolimod if you are pregnant. Fingolimod 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 Teva-Fingolimod 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 Teva-Fingolimod and for two months after you stop taking it.

If you do become pregnant while taking Teva-Fingolimod tell your healthcare professional doctor right away. You and your healthcare professional doctor will decide what is best for you and your baby. If you become pregnant while taking Teva-Fingolimod, you can call Teva Canada Ltd. at 1-800-268-4127 ext. 3

Breastfeeding: You should not breast-feed while you are taking Teva-Fingolimod. Teva-Fingolimod can pass into breast milk and there is a risk of serious side effects for you're a breast-fed baby.

Driving and using machines: After the first dose of Teva-Fingolimod, 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 Teva-Fingolimod.

Interactions with this medication

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 Teva-Fingolimod if you are taking, or have recently taken, medicines for an irregular heartbeat such as:

- quinidine
- disopyramide
- amiodarone
- sotalol

The following may interact with Teva-Fingolimod:

- Medicines for heart problems or high blood pressure.
- Medicines that slow down the heartbeat such as atenolol or metoprolol (called beta-blockers), such as verapamil, or diltiazem (called calcium channel blockers) 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. Teva-Fingolimod should not be started while you are on these medications. If you are switching to Teva-Fingolimod from another MS treatment, your healthcare provider 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 Teva-Fingolimod 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 should I take Teva-Fingolimod?

- Always take Teva-Fingolimod exactly as your healthcare professional has told you.
- Do not stop taking Teva-Fingolimod or change your dose without talking with your healthcare professional.
- Take Teva-Fingolimod once a day, at the same time each day with half a glass of water.
- Teva-Fingolimod can be taken with or without food. Teva-Fingolimod 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.
- Take one capsule per day (0.5 mg of fingolimod) taken orally (by mouth).
- Take Teva-Fingolimod once a day, at the same time each day with half a glass of water. Fingolimod can be taken with or without food.

What do I do if I miss a 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 Teva-Fingolimod 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 Teva-Fingolimod again after stopping for 2 weeks or more, you will need to start taking Teva-Fingolimod again in a medical setting. Do not restart Teva-Fingolimod after stopping it for more than two weeks without talking to your healthcare professional.

What do I do if I take too much Teva-Fingolimod?

If you think you or someone you are caring for may have taken too much Teva-Fingolimod, 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.

How should I store fingolimod?

How to store Teva-Fingolimod

- Do not use Teva-Fingolimod after the expiry date shown on the box.
- Store at room temperature.
- Store in the original package, protect from moisture.
- Keep out of reach and sight of children.

What are possible side effects of Teva-Fingolimod?

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

Side effects may include:

- Flu virus infection
- Headache
- Diarrhea
- Black 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

Talk to your healthcare professional if you experience any of the following:

- **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) These are not all the possible side effects that you may experience when taking Teva-Fingolimod. For a complete list of possible side effects, please consult the Patient Medication Information leaflet.

What should I do if I experience any of these signs?

If any of these affects you severely, tell your healthcare professional, nurse or pharmacist. If you experience any side effects that are not listed here, or in the **Consumer Information** leaflet, contact your healthcare professional.

Reporting side effects:

You can report any suspected adverse reactions associated with the use of Teva-Fingolimod to:

- **Teva Canada Limited** at 1-800-268-4127 option 3 (English), 1-877-777-9117 (French), Telefax: 1-416-335-4472; or

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/adverse-reaction-reporting.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.

If you want more information about Teva-Fingolimod:

- 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 <http://www.tevacanada.com>; or by calling 1-800-268-4127 ext. 3; or email druginfo@tevacanada.com.