Assessing Your Multiple Sclerosis (MS) Medication

If you have recently been switched to generic fingolimod capsules, here are some points to keep in mind while taking this medication:

Does the manufacturer of your generic fingolimod capsules change from month-to-month?

Make a note of the manufacturer information listed at the bottom section of the label, so you can keep track of this.

Are there differences in the capsules within the same bottle of medication?

Examine the capsules and take note of any changes or peculiarities in appearance, smell and taste.

Have you had new or worsened symptoms since switching to generic fingolimod capsules?

Contact your healthcare provider if you observe any new or worsening symptoms and adverse reactions. Some common symptoms of relapse are: changes in vision, numbness, tremors, spasms, difficulties in walking or balance, extreme fatigue, difficulty speaking, problems with memory or attention, and painful sensations.[1]

Learn more about MS relapses on page 2.

Keep track of any noticeable changes to your medication and symptoms. Providing accurate details to your healthcare provider can help them understand your condition and make adjustments to your care more effectively.

Why it matters

Research suggests generic fingolimod capsules, that do not meet FDA standards, may be putting patients at risk of increased MS activity and relapse.[2]

Six patients with relapsing-remitting MS had relapses, and higher absolute lymphocyte counts, within a year of switching to generic fingolimod capsules.[2] All patients were taking Gilenya® (fingolimod) capsules and relapse-free, from 6 months after treatment start on Gilenya® to their switch over to generic fingolimod capsules.

A closer look at their medication revealed that some of the generic capsules contained 25% less than the prescribed 0.5 mg of fingolimod, which could have led to increased lymphocyte activity and relapse.

There are currently 15 FDA-approved generic fingolimod capsules on the market,[3] but each product is produced by a different manufacturer to different quality standards. They are all available at pharmacies and substitutable for Gilenya®, which means it is difficult for your healthcare provider to ensure that your medication is consistent from month-to-month.

If you are worried about the consistency of your fingolimod product, speak to your healthcare provider about TASCENSO ODT® (fingolimod).

TASCENSO ODT is the fingolimod you can count on for consistent medication, and is accompanied by a wide-ranging patient support program, Cycle Vita™.

Please see the complete Important Safety Information on page 3.

Understanding MS Relapse

With MS, you may experience temporary changes in your symptoms that typically resolve within 24 hours.[1] However, if the new or worsening symptoms last for more than 24 hours, and are followed by complete or partial recovery, you may have had a relapse.

Relapse duration can last from days to months, and its presentation can range from mild to severe. Symptoms vary from person to person, and may be continuous or noncontinuous.[1]

Due to their variability, MS relapses are easily overlooked and missed in routine appointments. You can help your healthcare provider better understand your condition through proactive communication.

If you think you might be having an MS relapse, you might want to ask yourself the following questions:

- When did my symptoms begin, how are they making me feel, and how are they limiting or changing my daily activities and overall function?
- Have any changes been made to my MS-treatment plan?
- Has a new medication been added to my regimen for a condition not related to MS?
- Am I recovering from a recent infection?
- Have I recently experienced any significant changes in my life or stressful situations?
- Was I in a very warm environment?
- How would I describe my fatigue level, and my mood?

If you have experienced any changes in MS symptoms that lasted for more than 24 hours, speak to your healthcare provider about your condition, providing as much detail as possible.

Please see the complete Important Safety Information on page 3.

References:

1. MSAA. 2024. What is an MS relapse? MSAA. Available at: https://mymsaa.org/publications/ms-relapse-toolkit/what-relapse/. [Accessed Nov. 22nd 2024].
2. Okuda DT, Tardo LM, Wright CM. et al. 2024. *Clinical and radiological implications of subpotent generic fingolimod in multiple sclerosis: a case series.* Therapeutic Advances in Neurological Disorders. 2024;17. doi:10.1177/17562864241300047.
3. FDA., 2024. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available at www.accessdata.fda.gov/scripts/cder/ob/index.cfm. [Accessed Nov. 27 2024].

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Important Safety Information

Indications
TASCENSO ODT is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults and children 10 years of age and older.

Contraindications
Do not take TASCENSO ODT if:
- In the last 6 months you experienced heart attack, unstable angina, stroke or mini-stroke (transient ischemic attack or TIA), or certain types of heart failure.
- You have an irregular or abnormal heartbeat (arrhythmia), including a heart finding called prolonged QT as seen on an ECG, or if you take medicines that change your heart rhythm.
- You are allergic to fingolimod or any of the other ingredients.

Important Safety Information

Warnings and Precautions
TASCENSO ODT may cause serious side effects. TASCENSO ODT can slow your heart rate, therefore you will be monitored after the first dose. There is an increased risk of serious infections, some of which can be life threatening; contact your doctor if you develop any symptoms of infections. You may experience shortness of breath and increased blood pressure. Progressive Multifocal Leukoencephalopathy (PML), a rare brain infection, has occurred in patients taking fingolimod; call your doctor immediately if you experience symptoms including weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is confirmed, treatment should be stopped. Your doctor will monitor you for the development of Immune Reconstitution Inflammatory Syndrome (PML-IRIS), which has been reported in patients who stopped treatment after developing PML. Macular edema, a vision problem that can cause some of the same vision symptoms as an MS attack may occur; call your doctor immediately if you have any vision changes. TASCENSO ODT may cause liver damage; call your doctor immediately if you experience unexplained nausea, abdominal pain, fatigue, anorexia, jaundice and/or dark urine. Rare cases of Posterior Reversible Encephalopathy Syndrome in adults have been reported with fingolimod; call your doctor immediately if you experience sudden onset of severe headaches, altered mental status, visual disturbances or seizures. TASCENSO ODT may cause harm to your unborn baby; speak to your doctor before becoming pregnant. Stopping TASCENSO ODT may cause worsening of your MS symptoms, consult a doctor before stopping treatment. Malignancies have been associated with fingolimod treatment; limit exposure to sunlight and call your doctor if you have any changes in skin appearance. You may experience a hypersensitivity reaction; call your doctor if you experience rash, urticaria and angioedema. TASCENSO ODT remains in the blood and can continue to have effects up to two months after treatment.

Adverse Reactions
The most common side effects with fingolimod are headache, abnormal liver tests, diarrhea, cough, flu, inflammation of the sinuses, back pain, stomach pain, and pain in arms and legs.

If you have any new or worsening negative side effects whilst taking TASCENSO ODT you should immediately call your doctor.

Tell your doctor about all your medical conditions and all medicines you take, before starting treatment.

If you take too much TASCENSO ODT immediately call your doctor or go to the nearest hospital emergency room.

For more detailed information, please refer to the full Prescribing Information at www.tascenso.com/PI.

For more detailed information, please refer to the Medication Guide - www.tascenso.com/MG.

To report SUSPECTED ADVERSE REACTIONS, contact Cycle Pharmaceuticals Ltd at 1-888-533-1625 or the FDA at: 1-800-FDA-1088 or www.fda.gov/medwatch