Clinical and radiological outcomes of directed treatment transitions from Gilenya® to generic fingolimod

Study overview

The UT Southwestern Medical Centre conducted a retrospective analysis of 88 patients who transitioned from Gilenya® (fingolimod) to generic fingolimod capsules.[1] All patients had received Gilenya® capsules for over a year before switching and had been maintained on generic fingolimod capsules for at least six months, providing real-world insights into outcomes following the transition.[1]

While on generic fingolimod capsules:

Relapse rate was approximately

5 times higher

The average absolute lymphocyte count

increased by 8.81%

Time without MRI advancement was

reduced to 1.43 years

from 6.66 years on Gilenya® capsules[1]

The development rate of side effects per year was

2.45-fold higher

With 15 generic fingolimod capsules on the market, all AB-rated to Gilenya®,[2] **a prescription for Gilenya® or generic fingolimod capsules leaves the quality and consistency of your patients' treatment to chance.**

Learn more about an alternative fingolimod option on page 2.

References:

1. Patel, MA, et al. 2025, May 28-31. Clinical and Radiological Outcomes of Directed Treatment Transitions from Gilenya® to Generic Fingolimod [Poster]. CMSC Annual Meeting 2025, Phoenix, AZ, United States. Available at: https://cmsc.confex.com/cmsc/2025/meetingapp.cgi/Paper/10222. [Accessed September 3 2025] **2.** FDA., 2025. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available at www.accessdata.fda.gov/scripts/cder/ob/index.cfm. [Accessed: September 3 2025]. **3.** REF-00075 **4.** Wainwright, C, et al. 2023. Fingolimod: Assay analysis of US generic capsule products reveals variation in fingolimod content beyond the recommended acceptance criteria, Multiple Sclerosis and Related Disorders, Volume 80, 105077. doi:10.1016/j.msard.2023.105077

TASCENSO ODT® (fingolimod), *the fingolimod you can count on* for consistent medication, at the dosage you have prescribed, every time.

- TASCENSO ODT cannot be substituted at the pharmacy level, it is not a generic and not AB-rated to Gilenya®[2]
- Bioequivalent to Gilenya® capsules, with the same efficacy and safety profile[3]
- Manufactured in the UK, with each and every batch tested and verified, containing 100.3-100.8% of the label[4]
- Accompanied by a comprehensive patient support* program, Cycle Vita™, which delivers individualized medication access, financial, and product support

Learn more about TASCENSO ODT at www.tascenso.com

TASCENSO ODT®
(fingolimod)

Important Safety Information

Indications
TASCENSO ODT is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

Contraindications
- Patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure.
- Patients with a history or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker.
- Patients with a baseline QTc interval ≥ 500 msec.
- Patients with cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs.
- Patients who had a hypersensitivity to fingolimod or any excipients in TASCENSO ODT.

Concomitant use with other products containing fingolimod. Warnings and Precautions:
Due to a risk for bradyarrhythmia and AV blocks patients should be monitored during TASCENSO ODT treatment initiation. TASCENSO ODT may increase blood pressure, risk of infections and may cause fetal harm. Cases of Progressive Multifocal Leukoencephalopathy (PML) and of clinically significant liver injury have occurred in patients treated with fingolimod in the postmarketing setting. If PML is confirmed, treatment should be discontinued; Immune Reconstitution Inflammatory Syndrome (PML-IRIS) has been reported after discontinuation. TASCENSO ODT increases risk of macular edema. Rare cases of Posterior Reversible Encephalopathy Syndrome in adults have been reported with fingolimod. Fingolimod can have respiratory effects. Severe increase in disability accompanied by multiple new lesions on MRI has been reported following discontinuation of fingolimod. MS relapses with tumefactive demyelinating lesions on imaging have been observed during fingolimod therapy and after discontinuation. The risk of cutaneous malignancies (including basal cell carcinoma, squamous cell carcinoma, and melanoma) is increased in patients treated with S1P receptor modulators. Cases of lymphoma have been reported in patients receiving fingolimod. The reporting rate of non-Hodgkin lymphoma with fingolimod is greater than that expected in the general population. Fingolimod remains in the blood and has pharmacodynamic effects, including decreased lymphocyte counts for up to 2 months following the last dose. Hypersensitivity reactions including rash, urticaria, and angioedema have been reported with fingolimod. Cases of seizures, including status epilepticus, have been reported with the use of fingolimod.

Adverse Reactions:
In clinical trials, the most common adverse reactions (incidence ≥ 10% and >placebo) are headache, liver transaminase elevation, diarrhea, cough, influenza, sinusitis, back pain, abdominal pain, and pain in extremity.

Drug Interactions:
Patients on QT prolonging drugs with a known risk of torsades de pointes should be monitored during initiation of treatment with TASCENSO ODT. Monitor patients during use of systemic ketoconazole. Use of live attenuated vaccines during, and for 2 months after stopping TASCENSO ODT, should be avoided.

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

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.

*Some areas of support may not be accessible to all patients. Eligibility criteria may apply to ensure compliance with all applicable federal and state requirements, and benefits may be limited to commercially insured patients only. For more detailed information about eligibility, terms and conditions, please contact the Cycle Vita team at 888-360-8482.

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Support *for life*