TASCENSO ODT®
(fingolimod)
0.25 mg and 0.5 mg ODT

With TASCENSO ODT® it's time for convenience.

Indication
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.[1]

This material is intended for Healthcare Providers in the United States

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

Introducing TASCENSO ODT to the MS Community

TASCENSO ODT (orally disintegrating tablet) is an MS treatment with patients' needs in mind.

- Manufactured in the UK, with each and every batch tested and verified
- The same proven fingolimod you are familiar with[1]
- The first MS treatment available as an easy-to-swallow, orally disintegrating tablet[1]
- Accompanied by Cycle Vita™, our support platform dedicated to providing support to all your eligible* patients
- Not substitutable at the pharmacy level[3]

Important Safety Information[1]
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.

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

Bioequivalence studies

Under the FDA's 505(b)(2) pathway, TASCENSO ODT was shown to have the same pharmacokinetics (PK) profile as Gilenya® (fingolimod) capsules, meaning the rate and extent of exposure of the drug is the same for both formulations. Therefore, the two products are considered bioequivalent.[2]

- Same proven fingolimod
- Same safety, same efficacy and the same side effects
- Not a generic[3]

Not only could the unique formulation of TASCENSO ODT be well suited to your patients, it also means TASCENSO ODT cannot be substituted by Gilenya® or generic fingolimod at the pharmacy level.

Important Safety Information[1]
Cases of Progressive Multifocal Leukoencephalopathy 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.

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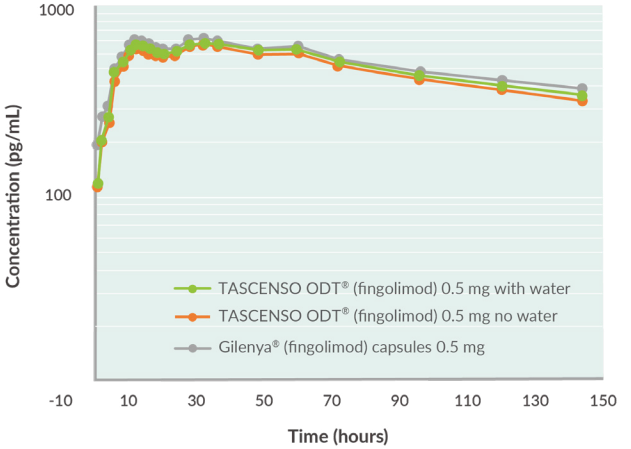
Gilenya® is a registered trademark of Novartis AG.

Bioequivalence studies

Fasted Study[2]

- Single center, randomized, single dose, laboratory blinded, single period, 3-treatment, 3-arm parallel study
- Test: TASCENSO ODT – 1 mg (2 x 0.5 mg ODT)
- Reference: Gilenya® – 1 mg (2 x 0.5 mg oral capsule)
- Treatment 1: 25 participants, single 1 mg dose of Test product, orally administered with 240 mL of water in the morning
- Treatment 2: 25 participants, single 1 mg dose of Test product, orally administered without water in the morning
- Treatment 3: 25 participants, single 1 mg dose of Reference product, orally administered with 240 mL of water in the morning

Bioequivalence data of Gilenya® (fingolimod) capsules 0.5 mg and TASCENSO ODT® (fingolimod) orally disintegrating tablets 0.5 mg, with and without water, under fasting conditions



Important Safety Information[1]
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.

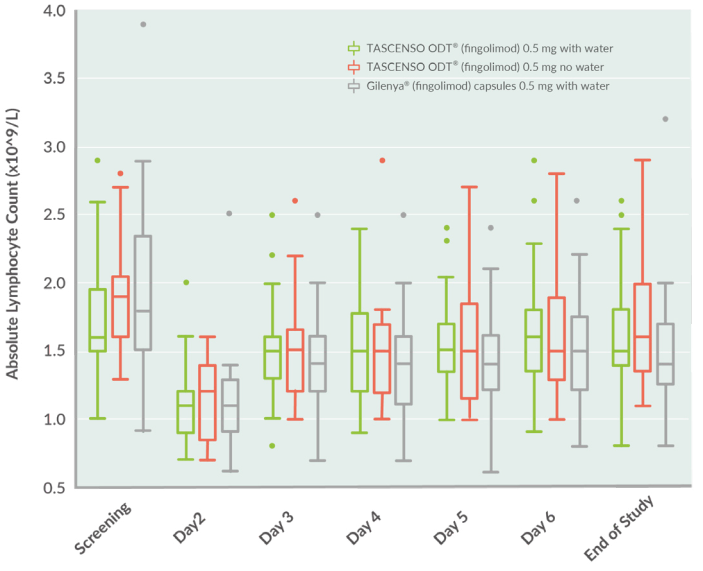
Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

PK and Statistical Results - Fasted Study[2]

FINGOLIMOD PK Parameter	TASCENSO ODT w/o water Geometric Mean Fasted	Gilenya® w/water Geometric Mean Fasted	Geometric Mean Ratio (90% CI) Target 80-125%
T_{max}(h) (min-max)	32.00 (10.00 – 58.87)	28.00 (12.00 – 59.03)	N/A
C_{max}(pg/mL) (SD)	689.0 (96.1)	761.6 (112.8)	90.54 (84.64-96.98)
AUC_{0-144}(pg.h/mL) (SD)	70875.8 (10224.8)	77952.1 (12029.5)	91.09 (84.66-98.01)

FINGOLIMOD PK Parameter	TASCENSO ODT w/ water Geometric Mean Fasted	TASCENSO ODT w/o water Geometric Mean Fasted	Geometric Mean Ratio (90% CI) Target 80-125%
T_{max}(h) (min-max)	32.00 (12.00 – 59.82)	32.00 (10.00 – 58.87)	N/A
C_{max}(pg/mL) (SD)	722.7 (126.9)	689.0 (96.1)	104.33 (96.71-112.56)
AUC_{0-144}(pg.h/mL) (SD)	74521.7 (15219.5)	70875.8 (10224.8)	104.19 (95.89-113.21)

Bioequivalence studies



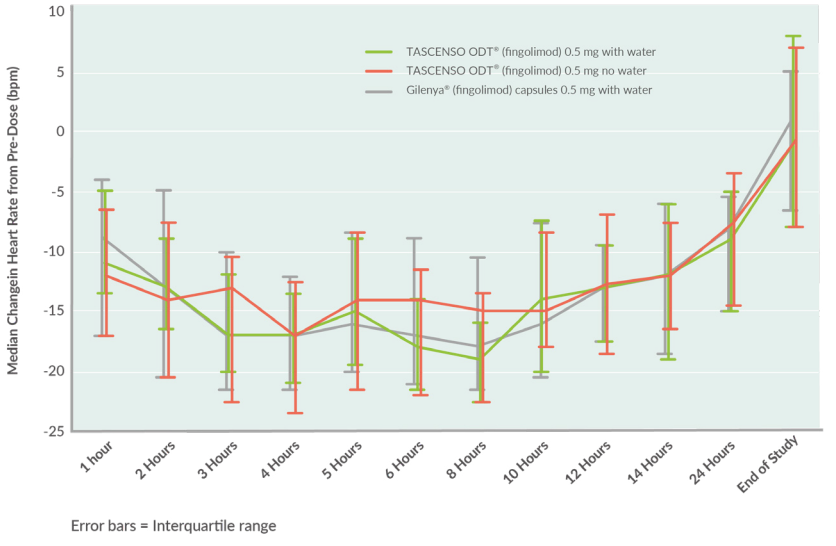
Absolute Lymphocyte Count

- 3 treatment groups with 25 participants in each group.
- TASCENSO ODT demonstrated a similar lowering of lymphocyte counts compared to Gilenya®.

Important Safety Information[1]
MS relapses with tumefactive demyelinating lesions on imaging have been observed during fingolimod therapy and after discontinuation. The risk of basal cell carcinoma and melanoma is increased in patients treated with fingolimod. Cases of lymphoma have been reported in patients receiving fingolimod.

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

Bioequivalence studies



Heart Rate

- Post-dose heart rate changes from baseline were compared between 3 treatment groups.
- 25 participants in each group.
- TASCENSO ODT demonstrated a similar effect on heart rate compared to Gilenya®.
- There were no differences in adverse events observed between TASCENSO ODT and Gilenya®.

Important Safety Information[1]
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.

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

With Convenience in Mind

Unique orally disintegrating tablet (ODT)

Dissolves on the tongue in seconds

No special storage conditions are required, the product should be stored at room temperature (68°F to 77°F) and protected from moisture[1]

Can be taken with or without food[1]

Provides flexibility for patients as it can be taken with or without water[1]

Taken once-daily

Important Safety Information[1]
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.

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

During a study of TASCENSO ODT:

100%
of participants agreed TASCENSO ODT was easy to tolerate.[4]

89%
of participants agreed they had an overall favorable opinion of TASCENSO ODT.[4]

100%
of participants felt TASCENSO ODT left a pleasant taste.[4]

82%
of participants agreed TASCENSO ODT had no bitter after-taste.[4]

Important Safety Information[1]
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.

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

Cycle Vita – Our Dedicated Support Team

Enroll your patients on TASCENSO ODT to gain access to the Cycle Vita team, who have decades of experience supporting patients with MS.

Your patients will have access to individualized support* such as:

- TASCENSO Time Program (In-home First Dose Observation and Baseline Assessments) (details on page 12)
- Bridge Program (details on page 13)
- Financial assistance (details on page 14)
- Medication adherence support (details on page 14)

Cycle Vita will provide relevant product information and processes support to initiate treatment as soon as possible.

CYCLE VITA™
Support *for life*

Important Safety Information[1]
Cases of Progressive Multifocal Leukoencephalopathy and of clinically significant liver injury have occurred in patients treated with fingolimod in the postmarketing setting. TASCENSO ODT increases risk of macular edema.

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.

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

The Cycle Vita Process

CYCLE VITA™
Support *for life*

New patient intake and enrollment support*

Benefit investigation
Coordinate between stakeholders to meet prior authorization and document requirements

Baseline Assessments (BA)‡
Providing access to in-home baseline assessments as necessary to **initiate eligible patients' treatment**

Prior authorization** and appeals
Facilitate the process of submission requirements, including **strengthening** denied submissions

Co-Pay assistance and reimbursement
Identification of any potential financial **assistance** options available to eligible patients

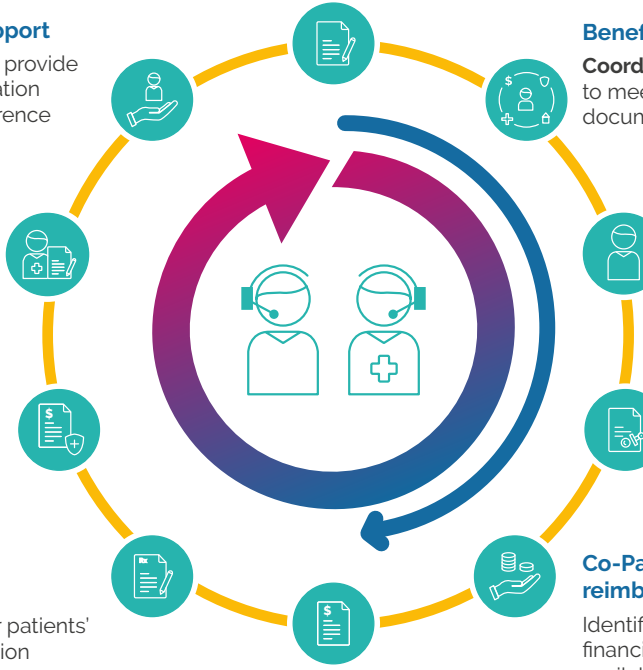
Benefit summary fax and call
Benefit **outcome shared** with HCP and patient

Route patient info & Rx to specialty pharmacy
Ensure an **uninterrupted supply** of your patients' therapy with the help of timely prescription renewal reminders

HCP field reimbursement support
In-office **education** for best practices of submissions and expectation setting for other logistics

First Dose Observation (FDO)‡
In-home FDO available to eligible patients, either at treatment initiation or following a lapse in treatment

Continuous clinical support
Registered Clinicians can provide disease state and medication training to facilitate adherence



‡ Partnered with industry leaders for in-home BA and FDOs, with capability to complete these services at a neutral site if necessary.

* Some areas of product support are treatment specific and 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.

** Cycle Vita cannot complete preauthorization, medical language or submissions for HCP. Cycle Vita can be expected to monitor progress of PA between the HCP and the Payor including submission and follow up reminders with both parties.

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

Cycle Vita features:

Hub Support* - Initiating treatment

Our **TASCENSO Time Program** provides a seamless, like-for-like in-home baseline assessment (BA) and first dose observation (FDO) experience for you and your patients.

Switching to TASCENSO ODT	Starting on TASCENSO ODT
For patients currently taking the same dose (0.25 mg or 0.5 mg) of another fingolimod treatment a FDO **will not** be required, providing the patient has not had a lapse in treatment for 14 days or more.[1]	Patients who are currently not on another fingolimod treatment or are increasing their dose (from 0.25 mg to 0.5 mg) **will** need to have BAs and a FDO to initiate therapy.[1]

Through the TASCENSO Time Program, eligible patients will have convenient access to in-home BAs and an FDO as necessary to initiate their treatment. Our team has extensive experience in the management and delivery of BAs and FDOs and is committed to supporting your patients during this process.

Our priority is to ensure patients experience a smooth transition from their current disease modifying therapy to TASCENSO ODT.

Important Safety Information[1]
Rare cases of Posterior Reversible Encephalopathy Syndrome in adults have been reported with fingolimod. Fingolimod can have respiratory effects.

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

Cycle Vita features:

Hub Support* - Bridge Program

Eligible patients who are switching to TASCENSO ODT from another fingolimod treatment will have access to our Bridge Program while Cycle Vita secures appropriate benefit verification and prior authorization.

It is available to patients with an urgent medical need for TASCENSO ODT, including:

- **New patients** – For new patients who are switching to TASCENSO ODT from another fingolimod treatment while Cycle Vita secures appropriate benefit verification and prior authorization, providing they have not had a lapse of two weeks or more in their medication.
- **Existing patients** – For existing patients who are experiencing a temporary disruption in TASCENSO ODT therapy due to changes in their insurance coverage.

Patients who are switching from another fingolimod treatment to TASCENSO ODT should not take both treatments at the same time. Once your patient starts TASCENSO ODT they should stop taking any other fingolimod treatment.

Important Safety Information[1]
Severe increase in disability accompanied by multiple new lesions on MRI has been reported following discontinuation of fingolimod.

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

Cycle Vita features:

Hub Support*

- **Co-pay Assistance Program** – Commercially insured eligible patients may pay as little as $0
- **Reimbursement Research Support** – Including Benefit Investigation and Prior Authorization
- **On-going First Dose Observation Support** – Eligible patients will have access to additional first dose observations required due to a lapse in therapy
- **Living Well with MS** – Resources available to support patients in living well with MS, including advice on general wellbeing, diet and physical activity, developed by our Registered Dietitians at Cycle Vita
- **Medication Adherence Support** – Registered Clinicians can provide disease state and medication training to facilitate adherence

Important Safety Information[1]
MS relapses with tumefactive demyelinating lesions on imaging have been observed during fingolimod therapy and after discontinuation. The risk of basal cell carcinoma and melanoma is increased in patients treated with fingolimod.

Cases of lymphoma have been reported in patients receiving fingolimod.

Please see the Important Safety information on page 15 and full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

Important Safety Information[1]

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.

Important Safety Information

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 basal cell carcinoma and melanoma is increased in patients treated with fingolimod. 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.

Please see accompanying full Prescribing Information at www.tascenso.com/pi and Medication Guide at www.tascenso.com/mg

Getting started with TASCENSO ODT

TASCENSO ODT is an MS treatment with convenience in mind.

- The same proven fingolimod you are familiar with[1]
- In a unique ODT formulation[1]
- Accompanied by Cycle Vita™, our support platform dedicated to providing support to all your eligible* patients

To get started, please complete a TASCENSO ODT enrollment form available at: www.tascenso.com/enroll.
If you have any questions, please contact the Cycle Vita team at +1 (888) 360-8482.

For further information visit www.tascenso.com and the Prescribing Information available at www.tascenso.com/PI

References

1. TASCENSO ODT (fingolimod). Prescribing Information. Cycle Pharmaceuticals Ltd
2. Data on File: REF-00075
3. FDA., 2022. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Accessed December 7th 2023. Available: www.accessdata.fda.gov/scripts/cder/ob/index.cfm
4. Data on file: REF-00068

* 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 +1 (888) 360-8482.

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