TASCENSO ODT®

(fingolimod)

0.25 mg and 0.5 mg ODT

It's time for you.

This guide will support you in taking TASCENSO ODT, whether you are new to fingolimod or are switching from another fingolimod treatment.

It also contains useful information about Cycle Vita™, our dedicated hub support platform, which delivers individualized support* for patients.

This brochure is intended for patients and caregivers in the US who have been prescribed TASCENSO ODT. It is provided for information purposes only. It is not intended to be, and should not be used as, a substitute for medical advice.

Please see the Important Safety Information on page 2 and Prescribing Information on pages 8-11.

Important Safety Information[1]

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 healthcare provider 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 healthcare provider 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 healthcare provider 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 healthcare provider immediately if you have any vision changes. TASCENSO ODT may cause liver damage; call your healthcare provider 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 healthcare provider 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 healthcare provider before becoming pregnant. Stopping TASCENSO ODT may cause worsening of your MS symptoms, consult your healthcare provider before stopping treatment. Malignancies have been associated with fingolimod treatment; limit exposure to sunlight and call your healthcare provider if you have any changes in skin appearance. You may experience a hypersensitivity reaction; call your healthcare provider 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 healthcare provider.

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

If you take too much TASCENSO ODT immediately call your healthcare provider 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.

Please see the Prescribing Information on pages 8-11.

Welcome, from Cycle Vita!

CYCLE VITA™
Support *for life*

With TASCENSO ODT, it's time for you.

At Cycle Vita, we understand that it can be challenging to access your medication, while keeping on top of everything else.

That's why TASCENSO ODT has your needs in mind. It is the first MS treatment available as an easy-to-swallow, orally disintegrating tablet, which could offer you greater convenience. We also provide continuous support* tailored to your needs, whether it is help accessing TASCENSO ODT from your insurance provider, guidance on how to take your medication, or supporting you with your baseline assessments and first dose observation where necessary.

We recognize TASCENSO ODT is only a small part of your life with MS, but we hope this will be a useful resource to you when taking your medication.

Best Wishes,

Cycle Vita

Scan the QR code below to read our Living Well with MS brochure which has wellbeing, healthy diet and exercise tips.

Indications
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TASCENSO ODT is:

- The same proven fingolimod that you may be familiar with.[1]
- Unique orally disintegrating tablet (ODT) formulation, which is not a generic.[1]
- FDA-Approved.
- Accompanied by Cycle Vita, our support platform for eligible* patients.

Taking TASCENSO ODT

- Be careful when opening the blister pack and take the ODT immediately.
- Do not store the TASCENSO ODT outside the blister pack for future use.
- Use dry hands.
- **Do not** push the ODT through the foil.
- A very small amount of product residue may remain inside the pack and the ODT may appear to have a feathered edge. This is normal and you will still receive the correct dose.
- Take orally once a day.
- Take with or without water.
- Take with or without food.
- **Take TASCENSO ODT exactly as your doctor tells you to take it.**

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.

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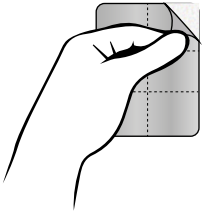
Taking TASCENSO ODT

Step 1

Do not push the orally disintegrating tablet (ODT) through the lidding foil.

Peel back the lidding foil from one blister, push the underside of the foil pocket to release the ODT and gently remove the ODT.



Step 2

As soon as the blister pack is opened, remove the ODT and place on the tongue and allow it to dissolve.

Important!

- If you take too much TASCENSO ODT, call your doctor or go to the nearest hospital emergency room right away.
- Do not stop taking TASCENSO ODT without talking with your doctor first.
- Call your doctor right away if you miss a dose of TASCENSO ODT. Missing doses may result in the need for a first dose observation, where you are observed by a healthcare provider for at least 6 hours when you take your next dose.

Contraindications
Do not take TASCENSO ODT if: 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.

Please see the Important Safety Information on page 2 and Prescribing Information on pages 8-11.

Introducing Cycle Vita

Our dedicated team of experts have decades of experience supporting patients with MS. When you are prescribed TASCENSO ODT you can expect financial, logistics and educational support from Cycle Vita, including:

- **Bridge Program:** If you are taking another fingolimod treatment, a free supply of TASCENSO ODT is available while we secure appropriate Benefit Verification and assist with Prior Authorization activities, providing there is an active collaboration with your clinic to pursue coverage. It may also be requested if you experience a temporary disruption in therapy due to insurance coverage.
- **Co-Pay Program:** If you are commercially insured, you may pay as little as $0.
- **Medical Adherence:** Registered Clinicians can provide you with training to help you keep on top of your medication schedule.

You can expect to hear from two different types of people at Cycle Vita:

Clinical specialists
provide you with clinical education, clinical support and medication administration support.*

Access specialists
help you access TASCENSO ODT through enrollment, financial and pharmacy support.*

Save the Cycle Vita number in your phone! 888-360-8482

You should expect to receive calls from the Cycle Vita team to support you in your treatment. Don't forget to save the number to your phone so you know to answer when they call.

Contraindications
Do not take TASCENSO ODT if: You are allergic to fingolimod or any of the other ingredients.

Please see the Important Safety Information on page 2 and Prescribing Information on pages 8-11.

The TASCENSO Time Program

If you are new to fingolimod, or have had a lapse in treatment for 14 days or more, our TASCENSO Time Program will provide a seamless in-home baseline assessments (BA) and first dose observation (FDO) experience for you.*

Your First Dose Observation

A healthcare provider will be with you for at least 6 hours after taking your first dose of TASCENSO ODT. Children will also be observed by a healthcare provider for at least 6 hours after taking their first dose of 0.5 mg of TASCENSO ODT when switching from the 0.25 mg dose.

Baseline Assessments

Assessments such as:

- Blood work.
- An ECG.
- An eye exam.
- Liver enzymes.

Find out more at TASCENSO.com

Important Safety Information[1]

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 healthcare provider if you develop any symptoms of infections.

Please see the Important Safety Information on page 2 and Prescribing Information on pages 8-11.

Summary of Information about TASCENSO ODT

What is TASCENSO ODT used for?

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

Who should not take TASCENSO ODT?

Do not take TASCENSO ODT if you:

- Have had a heart attack, chest pains, stroke, mini-stroke (transient ischemic attack), or heart failure in the last 6 months.
- Have a history of heart blockage or sick sinus syndrome, unless you have a pacemaker.
- Have certain types of irregular or abnormal heartbeat (arrhythmia), including patients in whom a heart finding called prolonged QT is seen on electrocardiogram ECG before starting TASCENSO ODT.
- Have an abnormal heartbeat that needs treatment with certain medications.
- Are allergic to fingolimod or any of the ingredients in TASCENSO ODT.
- Are taking any other medications containing fingolimod, the TASCENSO ODT active ingredient.

What warnings should I know about TASCENSO ODT?

Slower heart rate

TASCENSO ODT 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 TASCENSO ODT.

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

After you take your first dose of TASCENSO ODT, and after a child takes their first dose of 0.5 mg of TASCENSO ODT 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 symptoms of slow heart rate, they will usually happen during the first 6 hours after your first dose of TASCENSO ODT. Symptoms can happen up to 24 hours after you take your first dose of TASCENSO ODT.
- 6 hours after you take your first dose of TASCENSO ODT 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 TASCENSO ODT, 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 TASCENSO ODT 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 TASCENSO ODT.

Your slow heart rate will usually return to normal within 1 month after you start taking TASCENSO ODT. Call your healthcare provider 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 TASCENSO ODT, you may need to be observed by a healthcare professional when you take your next dose. Call your healthcare provider if you miss a dose of TASCENSO ODT.

Infections

TASCENSO ODT can increase your risk of serious infections that can be life-threatening and cause death.

You should not receive any live vaccines during treatment with TASCENSO ODT and for 2 months after you stop taking it. 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 TASCENSO ODT.

Due to risk of Human Papilloma Virus (HPV) infection please consult your healthcare provider for routine pap smear.

TASCENSO ODT lowers the number of white blood cells (lymphocytes) in your blood. This will usually return to normal within 2 months of stopping treatment. Your healthcare provider may do a blood test to check your white blood cells before starting TASCENSO ODT.

You should immediately call your healthcare provider if while taking TASCENSO ODT, or for 2 months after your last dose, you have a fever, tiredness, body aches, chills, nausea, vomiting, or a headache accompanied by fever, neck stiffness, sensitivity to light, nausea and/or confusion, as these could be symptoms of meningitis.

You will be monitored for infection during treatment and for 2 months after discontinuing TASCENSO ODT.

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. You should call your healthcare provider immediately if you have any new or worsening symptoms of PML that have lasted several days, including changes in your thinking or memory, changes in your vision, decreased strength, problems with balance, weakness on one side of your body, loss of coordination in your arms and legs, confusion or changes to your personality.

Your healthcare provider will monitor you for development of Immune Reconstitution Inflammatory Syndrome (PML-IRIS), which has been reported in patients who stopped treatment after developing PML. IRIS presents as a decline in your condition that may be rapid which can lead to serious neurological complications or death. After stopping TASCENSO ODT in the setting of PML, your healthcare provider will monitor you for development of PML-IRIS.

Macular edema

Macular edema is a vision problem that can cause some of the same vision symptoms as a multiple sclerosis (MS) attack (optic neuritis). If it occurs, it usually starts 3-4 months after starting TASCENSO ODT. Your healthcare provider should test your eyes around the time you start taking TASCENSO ODT, 3 to 4 months after you start taking TASCENSO ODT, periodically while you continue taking TASCENSO ODT and any time you notice vision changes during treatment. You have a higher risk of macular edema if you have diabetes or have had an inflammation of your eye (uveitis). Call your healthcare provider right away if you have blurriness, shadows, or a blind spot in the center of your vision, sensitivity to light, or unusually colored vision.

Liver damage

Your healthcare provider should do blood tests before and periodically during treatment with TASCENSO ODT. Immediately call your healthcare provider if you experience nausea, vomiting, stomach pain, tiredness, loss of appetite, dark colored urine, or if your skin or the whites of your eyes turn yellow.

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is swelling and narrowing of the blood vessels in your brain. It has happened rarely in adults taking TASCENSO ODT. Symptoms of PRES usually get better when you stop taking TASCENSO ODT. However, if left untreated it can lead to a stroke. Call your healthcare provider right away if you experience symptoms such as: sudden severe headache, sudden confusion, seizures or sudden vision loss or other changes in your vision.

Summary of Information about TASCENSO ODT, continued.

Breathing problems

Some patients who take TASCENSO ODT have shortness of breath. Call your healthcare provider right away if you have new or worsening breathing problems.

Pregnancy

You should avoid becoming pregnant whilst taking TASCENSO ODT and for 2 months after stopping taking it because of the risk of harm to the baby. Please consult your healthcare provider before getting pregnant.

Severe worsening of Multiple Sclerosis after stopping TASCENSO ODT

Many people who experience worsening of MS symptoms after stopping TASCENSO ODT do not return to the level of function they had before or during treatment. This can occur in women stopping due to pregnancy or planning for pregnancy. Worsening of symptoms most often occurs within 12 weeks after stopping TASCENSO ODT but can happen later. Always consult a healthcare professional before stopping treatment with TASCENSO ODT. Let your healthcare provider know if you have worsening symptoms of MS after stopping treatment.

Tumefactive Multiple Sclerosis

Some patients who have experienced severe worsening symptoms of MS whilst taking TASCENSO ODT or after discontinuation, have reported tumefactive multiple sclerosis. Your healthcare provider may evaluate you for tumefactive MS.

Blood pressure increase

You may experience high blood pressure, so your blood pressure will be continuously monitored throughout treatment.

Types of skin cancer called Basal Cell Carcinoma (BCC) and Melanoma

Tell your healthcare provider if you have any changes in the appearance of your skin, including changes to moles, new darkened areas on your skin, a sore that does not heal, growths such as bumps that may be shiny, pearly white, skin colored, or pink. Your healthcare provider should check your skin for any changes during treatment with TASCENSO ODT. Limit the amount of time you spend in sunlight and ultraviolet (UV) light. Wear protective clothing and use sunscreen with high sun protection factor.

Immune system effects

TASCENSO ODT can weaken your immune system during treatment and up to 2 months after your last dose.

What should I tell my healthcare provider?

Before you take TASCENSO ODT, tell your healthcare provider about all your medical conditions, including if you had or now have:

- An irregular or abnormal heartbeat (arrhythmia).
- A history of stroke or mini-stoke.
- 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 take or have taken medicines that lower your immune system.
- Recently received a vaccine or are scheduled to receive a vaccine.
- Chicken pox or have received the vaccine for chicken pox. Your healthcare provider may do a blood test for chicken pox virus. You may need to get the full course of the vaccine for chickenpox and then wait 1 month before you start taking TASCENSO ODT.
- Your child has completed their vaccination schedule. Your child needs to have completed their vaccination schedule before starting treatment with TASCENSO ODT.
- Eye problems, especially an inflammation of the eye called uveitis.
- Diabetes.
- Breathing problems, including during your sleep.
- Liver problems.
- High blood pressure.

- Any type of skin cancer, including basal cell carcinoma (BCC), melanoma, or squamous cell carcinoma (SCC).
- Are pregnant or plan to become pregnant. TASCENSO ODT may harm your unborn baby. Talk to your healthcare provider if you are pregnant or are planning to become pregnant. Tell your healthcare provider right away if you become pregnant while taking TASCENSO ODT or if you become pregnant within 2 months after you stop taking TASCENSO ODT.
    - You should stop taking TASCENSO ODT 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 TASCENSO ODT and for at least 2 months after you stop taking TASCENSO ODT.
- Are breastfeeding or plan to breastfeed. It is not known if TASCENSO ODT passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take TASCENSO ODT.

What are the side effects of TASCENSO ODT?

The most common side effects of TASCENSO ODT include:

- Headache
- Abnormal liver tests
- Diarrhea
- Cough
- Flu
- Inflammation of the sinuses
- Back pain
- Stomach pain
- Pain in arms or legs

Tell your healthcare provider if you have any side effects that bother you or that do not go away.

These are not all of the possible side effects of TASCENSO ODT. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What other medications might interact with TASCENSO ODT?

- Tell your healthcare provider if you take medicines that affect your immune system, including corticosteroids, or have taken them in the past.
- You will be monitored overnight if you are taking drugs such as citalopram, chlorpromazine, haloperidol, methadone, erythromycin.
- Tell your healthcare provider if you are taking Ketoconazole.
- Avoid live attenuated vaccines during, and for 2 months after stopping TASCENSO ODT treatment.
- **Do not take TASCENSO ODT with Gilenya or other medicines containing fingolimod.**

You are encouraged to report negative side effects of prescription drugs.

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.

This information is not comprehensive.

How to get more information:

- Talk to your healthcare provider or pharmacist
- Visit www.tascenso.com/pi to obtain the FDA-approved product labeling
- Call +1 888-533-1625

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

Useful resources

- TASCENSO ODT
  www.tascenso.com
- Cycle Vita
  www.cyclevita.life
- National MS Society
  www.nationalmssociety.org
- Multiple Sclerosis Association of America (MSAA)
  www.mymsaa.org

Find us on TASCENSO / CycleVitaUSA

Find us on tascenso_ODT_fingolimod

A friendly, familiar team is waiting here at Cycle Vita:

888-360-8482 | hello@cyclevita.life | www.cyclevita.life

CYCLE VITA™
Support for life

Reference

1. TASCENSO ODT (fingolimod). Prescribing Information. Cycle Pharmaceuticals Ltd

* 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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