PATIENT & CAREGIVER EDUCATION

Fingolimod

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Gilenya; Tascenso ODT

Brand Names: Canada

ACH-Fingolimod; APO-Fingolimod; Gilenya; JAMP Fingolimod; MAR-Fingolimod [DSC]; MYLAN-Fingolimod; PMS-Fingolimod; SANDOZ Fingolimod; TARO-Fingolimod; TEVA-Fingolimod [DSC]

What is this drug used for?

- It is used to treat MS (multiple sclerosis).

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.

- If you have ever had any of these health problems: Certain types of abnormal heartbeats (heart block, sick sinus syndrome, slow heartbeat, long QT on ECG), chest pain (angina), heart attack, heart failure, brain blood vessel disease (like transient ischemic attack [TIA] or stroke), high blood pressure, or sleep apnea.
- If you have had the varicella (chickenpox) vaccine in the past month.
- If you are getting any kind of light therapy, talk with your doctor.
- If you are taking another drug that has the same drug in it.
- If you are taking or have recently taken any drugs that can cause a slow heartbeat, a certain type of abnormal heartbeat (prolonged QT interval), or suppress your immune system. There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of

any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- Have your blood work and heart function checked as you have been told by your doctor. You will also need to have eye and skin exams.
- High blood pressure has happened with this drug. Have your blood pressure checked as you have been told by your doctor.
- Your doctor may order an MRI scan before you start this drug.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- If you have not had chickenpox or a chickenpox vaccine, talk with your doctor.
- If you are not up to date with all of your vaccines, talk

with your doctor. You may need to have some vaccines before treatment with this drug.

- Talk with your doctor before getting any vaccines while you take this drug and for 2 months after you stop it. Use with this drug may either raise the chance of an infection or make the vaccine not work as well.
- This drug stays in the body and may affect your immune system for up to 2 months after your last dose. If you will be taking another drug that will suppress your immune system within 2 months after you stop this drug, talk with your doctor.
- You may have more chance of getting an infection while you take this drug and for 2 months after you stop it. Some infections have been severe and even deadly. Wash hands often. Stay away from people with infections, colds, or flu.
- HPV infections have happened with this drug. This includes HPV-related growths and cancer. You may need to have an HPV vaccine before taking this drug. Have Pap smears as you have been told by your doctor.
- When this drug is stopped, MS signs can come back and may be worse than before or during treatment. Many people do not go back to the same level of function they had before this drug was stopped. Most of the time, this

effect happened in the first 12 weeks after stopping this drug but can happen later. If you stop this drug and your MS signs get worse, call your doctor right away.

- A raised risk of skin cancer has happened with this type of drug. Avoid lots of sun, sunlamps, and tanning beds. Use sunscreen with a high SPF and wear clothing that protects you from the sun.
- Liver problems have happened with this drug. Sometimes, this has been very bad and a liver transplant has been needed. Talk with the doctor.
- This drug may cause harm to an unborn baby. A pregnancy test will be done before you start this drug to show that you are NOT pregnant.
- If you may become pregnant, use birth control while taking this drug and for 2 months after your last dose. If you get pregnant, call your doctor right away.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or

symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of herpes infections like cold sores, shingles, genital sores, severe headache, confusion, change in eyesight, eye redness, or eye pain.
- Signs of meningitis like headache with fever, stiff neck, upset stomach, confusion, or if lights bother the eyes.
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of skin cancer like a new wart, lump, or other skin growth; a sore that bleeds or does not heal; a shiny, white, pink, red, or skin-colored bump that bleeds or does not heal; or a change in the color or size of a mole.
- Signs of high or low blood pressure like very bad headache or dizziness, passing out, or change in

eyesight.

- Chest pain or pressure.
- Shortness of breath.
- Trouble breathing that is new or worse.
- Slow heartbeat and a heartbeat that does not feel normal may happen when first starting this drug. Most of the time, this happens within 6 hours of your first dose. Sometimes, this can happen up to 24 hours after your first dose. Call your doctor right away if you have dizziness, slow heartbeat or a heartbeat that does not feel normal, or tiredness.
- An eye problem called macular edema has happened with this drug. The risk may be higher if you have diabetes or have had uveitis. Over a long period of time (like 6 months), macular edema can lead to lasting loss of eyesight. Call your doctor right away if light bothers your eyes or if you have abnormal colors in your eyesight; blurriness, shadows, or a blind spot in the middle of your eyesight; or any other changes in eyesight.
- A very bad and sometimes deadly brain problem called posterior reversible encephalopathy syndrome (PRES) has happened with this drug. Call your doctor right away if you have signs like feeling confused, lowered

alertness, change in eyesight, loss of eyesight, seizures, or very bad headache.

- A severe brain problem called progressive multifocal leukoencephalopathy (PML) may happen with this drug. This may be more likely the longer you take this drug. Signs can get worse even months after you stop this drug. PML may cause disability or can be deadly. Tell your doctor right away if you have signs like confusion, memory problems, depression, change in the way you act, change in strength on 1 side is greater than the other, trouble speaking or thinking, change in balance, or change in eyesight.
- Lymphoma has happened with this drug. Call your doctor right away if you have a big weight loss, night sweats, or swollen glands.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Flu-like signs.
- Stomach pain or diarrhea.

- Back pain.
- Pain in arms or legs.
- Sinus pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- The first dose is given in a doctor's office or hospital. This will also be done if you are starting this drug again after stopping it for some time. You will be watched for at least 6 hours after the first dose of this drug. Some people may need to be watched overnight. Before starting this drug, tell your doctor about all of your other drugs and health problems.

- Take with or without food.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Do not stop taking this drug without calling the doctor who ordered it for you.

Oral-disintegrating tablet:

- Peel back the foil on the blister. Do not push the tablet out of the foil when opening. Use dry hands to take it from the foil. Place on your tongue and let it dissolve. Water is not needed. Do not chew, break, or crush the tablet.
- Do not take this drug out of the blister pack until you are ready to take it. Take this drug right away after opening the blister pack. Do not store the removed drug for future use.

What do I do if I miss a dose?

- If you miss a dose, call your doctor right away.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.

- Store this drug in the original bottle or blister pack that it comes in.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.

- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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