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 the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor

about the allergy and what signs your child had.

- If your child has 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 your child has had the varicella vaccine in the past month.
- If your child is getting any kind of light therapy, talk with the doctor.
- If your child is taking another drug that has the same drug in it.
- If your child is taking or has recently taken any drugs that can cause a slow heartbeat, a certain type of abnormal heartbeat (prolonged QT interval), or suppress the immune system. There are many drugs that can do this. Ask the 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 the doctor and pharmacist about all of your child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it

is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- Have your child avoid tasks or actions that call for alertness until you see how this drug affects your child. These are things like riding a bike, playing sports, or using items such as scissors, lawnmowers, electric scooters, toy cars, or motorized vehicles.
- Have your child's blood work and heart function checked as you have been told by the doctor. Your child will also need to have eye and skin exams.
- High blood pressure has happened with this drug. Have your child's blood pressure checked as you have been told by the doctor.
- Your child's doctor may order an MRI scan before your child starts this drug.
- This drug may affect certain lab tests. Tell all of your child's health care providers and lab workers that your

child takes this drug.

- If your child has not had chickenpox or a chickenpox vaccine, talk with your child's doctor.
- If your child is not up to date with vaccines, talk with your child's doctor. Your child may need to have some vaccines before treatment with this drug.
- Talk with your child's doctor before your child gets any vaccines while taking this drug and for 2 months after your child stops taking it. Vaccine 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 child's immune system for up to 2 months after the last dose. If your child will be taking another drug that will suppress the immune system within 2 months after stopping this drug, talk with the doctor.
- Your child may have more chance of getting an infection while taking this drug and for 2 months after stopping it. Some infections have been severe and even deadly. Have your child wash hands often. Have your child stay away from people with infections, colds, or flu.
- HPV infections have happened with this drug. This includes HPV-related growths and cancer. Your child may need to have an HPV vaccine before taking this

drug. Have your child get Pap smears as you have been told by the 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 your child stops this drug and your child's MS signs get worse, call your child's doctor right away.
- A raised risk of skin cancer has happened with this type of drug. Have your child avoid lots of sun, sunlamps, and tanning beds. Use sunscreen with a high SPF and dress your child in clothing that protects 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.
- If your child is of childbearing age, a pregnancy test will need to be done before starting this drug to make sure your child is not pregnant.

If your child is or may be sexually active:

- If your child may become pregnant, have your child use birth control while taking this drug and for 2 months

after the last dose. If your child becomes pregnant, call the doctor right away.

If your child is pregnant or breast-feeding a baby:

- This drug may cause harm to the unborn baby if your child takes it during pregnancy.
- Tell the doctor if your child is breast-feeding a baby. You will need to talk about any risks to the baby.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has 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 an abnormal heartbeat may happen when first starting this drug. Most of the time, this happens within 6 hours of the first dose. Sometimes, this can happen up to 24 hours after the first dose. Call your child's doctor right away if your child has dizziness, slow

heartbeat, 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 your child has diabetes or has had uveitis. Over a long period of time (like 6 months), macular edema can lead to lasting loss of eyesight. Call the doctor right away if light bothers your child's eyes or if your child sees abnormal colors; has blurriness, shadows, or a blind spot in the middle of their eyesight; or has any other changes in eyesight.
- A severe and sometimes deadly brain problem called posterior reversible encephalopathy syndrome (PRES) has happened with this drug. Call the doctor right away if your child has signs like feeling confused, lowered alertness, change in eyesight like loss of eyesight, seizures, or severe headache.
- A severe brain problem called progressive multifocal leukoencephalopathy (PML) may happen with this drug. This may be more likely the longer your child takes this drug. Signs can get worse even months after your child stops this drug. PML may cause disability or can be deadly. Tell the doctor right away if your child has signs like confusion, memory problems, depression, change in the way your child acts, 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 child's doctor right away if your child has 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 child's doctor or get medical help if any of these side effects or any other side effects bother your child 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 child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's 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 the dose is raised, or if your child is starting this drug again after stopping it for some time. Your child 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 child's doctor about all of your child's other drugs and health problems.
- Give this drug with or without food.
- Keep giving this drug to your child as you have been told by your child's doctor or other health care provider, even if your child feels well.
- Do not stop giving this drug without calling the doctor who ordered it for your child.

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 child's tongue and have your child let it dissolve. Water is not needed. Do not let your

child chew, break, or crush the tablet.

- Do not take this drug out of the blister pack until you are ready to give this drug to your child. Give this drug right away after opening the blister pack. Do not store the removed drug for future use.

What do I do if my child misses a dose?

- If your child misses a dose, call the 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.

- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's doctor, nurse, 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.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any

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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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