EDUCACIÓN PARA PACIENTES Y CUIDADORES

Dimethyl Fumarate

This information from Lexicomp® 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
Tecfidera

Brand Names: Canada
ACH-Dimethyl Fumarate; APO-Dimethyl Fumarate; GLN-Dimethyl Fumarate; JAMP-Dimethyl Fumarate; MAR-Dimethyl Fumarate; PMS-Dimethyl Fumarate; Sandoz Dimethyl Fumarate; Tecfidera

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 are taking any of these drugs: Diroximel fumarate or monomethyl fumarate.

This drug may interact with other drugs or health problems.

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.

- Have your blood work and other lab tests checked as you have been told by your doctor.

- Herpes zoster (shingles) and other severe infections have happened with this drug. Sometimes, these infections have affected the brain, nerves, and other areas of the body. Talk with your doctor about what signs to watch for.
• Talk with your doctor before getting any vaccines. Use of some vaccines with this drug may raise the chance of an infection.

• Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the 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 liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
A severe brain problem called progressive multifocal leukoencephalopathy (PML) has happened with this drug. It 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.

Low white blood cell counts have happened with this drug. This may lead to a higher chance of getting an infection. In some people, the low white blood cell counts were severe and lasted for a long time. Tell your doctor if you have ever had a low white blood cell count. Call your doctor right away if you have signs of infection like fever, chills, or sore throat.

Rarely, severe stomach or bowel problems have happened with drugs like this one. Sometimes, this has been deadly. This includes bleeding, blockage, tears, or ulcers. Most of the time, this happened within the first 6 months after starting the drug. Call your doctor right away if you have rectal bleeding; bloody diarrhea; coughing or throwing up blood; throw up that looks like coffee grounds; or severe stomach pain, diarrhea, or throwing up.
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:

- Flushing (redness, warmth, itching, or burning).
- Diarrhea, stomach pain, upset stomach, or throwing up.

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.

- Take with or without food.
- Swallow whole. Do not chew, open, or crush.
• This drug may cause flushing. Taking this drug with food or taking aspirin 30 minutes before this drug may lower how often flushing happens. Aspirin may also lower how bad flushing is when it happens. Talk with your doctor to see if you can take aspirin while you are taking this drug.

**What do I do if I miss a dose?**

• Take a missed dose as soon as you think about it.
• If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
• Do not take 2 doses at the same time or extra doses.

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

• Store at room temperature protected from light. Store in a dry place. Do not store in a bathroom.
• Store in original container.
• 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.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your 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.

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