

Questions to Ask Your Doctor

Having a successful doctor visit means remembering to ask all the questions you wanted to. Below you will find some questions you can use to find out more about TECFIDERA, and how it may help your relapsing MS.

Discuss taking a pill

- Can we discuss an oral treatment like TECFIDERA?
- What are the potential benefits and risks of TECFIDERA?

TECFIDERA effectiveness

- I've heard TECFIDERA can significantly cut relapses. Can you tell me about the clinical study results for TECFIDERA?
- Can you explain how TECFIDERA has been shown to delay the progression of physical disability?
- Based on my last MRI, could TECFIDERA be an option for me?
- What could TECFIDERA do for my relapsing MS?

Taking TECFIDERA

- What are the possible side effects of TECFIDERA?
- What are the common side effects of TECFIDERA and how long do they usually last?
- What should I do if I experience side effects?
- Will I need to take any lab tests to monitor how I'm doing with TECFIDERA?

Next steps

- I'm interested in taking TECFIDERA for my relapsing MS. Now what?
- What kind of support is available during treatment with TECFIDERA?
- When should I schedule my follow-up appointments?

Tecfidera® (dimethyl fumarate) is a prescription medicine used to treat people with relapsing forms of multiple sclerosis.

Selected Important Safety Information

Do not use TECFIDERA if you have had an allergic reaction to TECFIDERA or any of its ingredients. TECFIDERA may cause serious side effects, including allergic reactions, PML, which is a rare brain infection that usually leads to death or severe disability, decreases in your white blood cell count, and liver problems. Your doctor should do blood tests to check your white blood cell count and liver function before you take TECFIDERA and from time to time during treatment. The most common side effects are flushing and stomach problems. Tell your doctor if you are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

For additional important safety information, please see next page and full [Prescribing Information](#) and [Patient Information](#). This file is an electronic PDF from Tecfidera.com.



The next step is talking TECFIDERA with your doctor.
Take this discussion guide to your next appointment.

Important Safety Information

Do not use TECFIDERA if you have had an allergic reaction (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing) to TECFIDERA or any of its ingredients.

Before taking and while you take TECFIDERA, tell your doctor about any low white blood cell counts or infections or any other medical conditions.

What are the possible side effects of TECFIDERA?

TECFIDERA may cause serious side effects including:

- **Allergic reactions**
- **PML, which is a rare brain infection that usually leads to death or severe disability.**
- **Decreases in your white blood cell count.** Your doctor should check your white blood cell count before you take TECFIDERA and from time to time during treatment
- **Liver problems.** Your doctor should do blood tests to check your liver function before you start taking TECFIDERA and during treatment if needed. Tell your doctor right away if you get any symptoms of a liver problem during treatment, including:
 - severe tiredness
 - loss of appetite
 - pain on the right side of your stomach
 - dark or brown (tea color) urine
 - yellowing of your skin or the white part of your eyes

The most common side effects of TECFIDERA include flushing and stomach problems. These can happen especially at the start of treatment and may decrease over time. Taking TECFIDERA with food may help reduce flushing. Call your doctor if these symptoms bother you or do not go away. Ask your doctor if taking aspirin before taking TECFIDERA may reduce flushing.

These are not all the possible side effects of TECFIDERA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov.**

Tell your doctor if you are pregnant or plan to become pregnant, or breastfeeding or plan to breastfeed. It is not known if TECFIDERA will harm your unborn baby or if it passes into your breast milk. Also tell your doctor if you are taking prescription or over-the-counter medicines, vitamins, or herbal supplements. If you take too much TECFIDERA, call your doctor or go to the nearest hospital emergency room right away.

For additional important safety information, please see full [Prescribing Information](#) and [Patient Information](#). This is not intended to replace discussions with your doctor.



Patient Information
TECFIDERA® (tek" fi de' rah)
(dimethyl fumarate) delayed-release capsules

What is TECFIDERA?

- TECFIDERA is a prescription medicine used to treat people with relapsing forms of multiple sclerosis (MS)
- It is not known if TECFIDERA is safe and effective in children under 18 years of age

Who should not take TECFIDERA?

- Do not use TECFIDERA if you have had an allergic reaction (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing) to TECFIDERA or any of its ingredients. See below for a complete list of ingredients.

Before taking and while you take TECFIDERA, tell your doctor if you have or have had:

- low white blood cell counts or an infection
- any other medical conditions

Tell your doctor if you are:

- pregnant or plan to become pregnant. It is not known if TECFIDERA will harm your unborn baby.
 - If you become pregnant while taking TECFIDERA, talk to your doctor about enrolling in the TECFIDERA Pregnancy Registry. You can enroll in this registry by calling 1-866-810-1462 or visiting www.tecfiderapregnancyregistry.com. The purpose of this registry is to monitor the health of you and your baby.
- breastfeeding or plan to breastfeed. It is not known if TECFIDERA passes into your breast milk. You and your doctor should decide if you will take TECFIDERA or breastfeed.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements

How should I take TECFIDERA?

- Take TECFIDERA exactly as your doctor tells you to take it
- The recommended starting dose is one 120 mg capsule taken by mouth 2 times a day for 7 days
- The recommended dose after 7 days is one 240 mg capsule taken by mouth 2 times a day
- TECFIDERA can be taken with or without food
- Swallow TECFIDERA whole. Do not crush, chew, or sprinkle capsule contents on food.
- Protect TECFIDERA from light. You can do this by storing the capsules in their original container.
- If you take too much TECFIDERA, call your doctor or go to the nearest hospital emergency room right away.

What are the possible side effects of TECFIDERA?

TECFIDERA may cause serious side effects including:

- **allergic reaction** (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing)
- **PML** a rare brain infection that usually leads to death or severe disability
- **decreases in your white blood cell count** Your doctor should do a blood test before you start treatment with TECFIDERA and while on therapy.
- **liver problems.** Your doctor should do blood tests to check your liver function before you start taking TECFIDERA and during treatment if needed. Tell your doctor right away if you get any of these symptoms of a liver problem during treatment.
 - severe tiredness
 - loss of appetite
 - pain on the right side of your stomach
 - have dark or brown (tea color) urine
 - yellowing of your skin or the white part of your eyes

The most common side effects of TECFIDERA include:

- flushing, redness, itching, or rash
- nausea, vomiting, diarrhea, stomach pain, or indigestion
- Flushing and stomach problems are the most common reactions, especially at the start of therapy, and may decrease over time. Taking TECFIDERA with food may help reduce flushing. Call your doctor if you have any of these symptoms and they bother you or do not go away. Ask your doctor if taking aspirin before taking TECFIDERA may reduce flushing. These are not all the possible side effects of TECFIDERA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to daily.med.nlm.nih.gov.**

General Information about the safe and effective use of TECFIDERA

- Medicines are sometimes prescribed for purposes other than those listed in this Patient Information. Do not use TECFIDERA for a condition for which it was not prescribed. Do not give TECFIDERA to other people, even if they have the same symptoms that you have. It may harm them.
- If you would like more information, talk to your doctor or pharmacist. You can ask your doctor or pharmacist for information about TECFIDERA that is written for healthcare professionals.

What are the ingredients in TECFIDERA?

Active ingredient: dimethyl fumarate

Inactive ingredients: microcrystalline cellulose, silicified microcrystalline cellulose, croscarmellose sodium, talc, silica colloidal silicon dioxide, magnesium stearate, triethyl citrate, methacrylic acid copolymer - Type A, methacrylic acid copolymer dispersion, simethicone (30% emulsion), sodium lauryl sulphate, and polysorbate 80.

Capsule Shell: gelatin, titanium dioxide, FD&C blue 1; brilliant blue FCF, yellow iron oxide and black iron oxide.

Manufactured by: Biogen Inc., Cambridge, MA 02142, www.TECFIDERA.com or call 1-800-456-2255

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 1/2017