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Tecfidera

## Tecfidera ⊲

Pronunciation: tek" fi de' rah

Generic name: dimethyl fumarate [ dye-METH-il-FUE-mar-ate ]

Dosage form: delayed-release capsules (120 mg, 240 mg)

Drug class: Selective immunosuppressants

Medically reviewed by Melisa Puckey, BPharm. Last updated on Aug 9, 2024.

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### What is Tecfidera?

Tecfidera (dimethyl fumarate) is used to treat relapsing forms of multiple sclerosis (MS) to help you have fewer relapses, delay the progression of disability, and slow brain lesion development. Tecfidera may help delay the progression of relapsing forms of MS, but it will not cure it.

Tecfidera is a delayed-release capsule that is taken twice daily, it is available as 120 mg or 240 mg of dimethyl fumarate.

Multiple sclerosis is a long-term condition that affects the brain and the spinal cord (central nervous system). It is caused by your immune system mistakenly attacking the protective covers (myelin sheaths) that surround the nerves of the spinal cord and brain. The inflammation and damage disrupt communication between the brain and other parts of the body, causing MS symptoms, including walking difficulties, feeling off balance, and blurred or double vision. In relapsing forms of multiple sclerosis, there are flare-ups (relapses or attacks) of symptoms followed by periods of remission when symptoms stabilize or are no longer noticeable.

Tecfidera reduces inflammation and damage to nerves that are caused by the immune system attacking the myelin sheath. It is not known exactly how it works, but it is thought Tecfidera's mechanism of action is the active ingredient dimethyl fumarate (DMF) and its metabolite, monomethyl fumarate (MMF) activates a pathway that is involved in oxidative stress, called the Nrf2 (Nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway.

Tecfidera is FDA-approved for the treatment of relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. It received FDA approval on March 27, 2013, for Biogen Inc., Cambridge, MA 02142.

A Tecfidera generic is now available under the active ingredient name dimethyl fumarate.

## Tecfidera side effects

### Common side effects

Common Tecfidera side effects include:

- stomach pain, indigestion, nausea, vomiting, diarrhea,
- · redness, rash, itching, or
- flushing (sudden warmth, redness, or tingly feeling).

#### **Flushing**

Flushing is one of the most common side effects of Tecfidera and symptoms may include a feeling of warmth, redness, itching, and a burning sensation. These symptoms generally begin soon after starting to take capsules and usually improve or resolve over time. Flushing affected 40% of patients compared to only 6% of patients taking a placebo in clinical trials. Usually, flushing side effect symptoms are mild or moderate, and less than 1% have serious flushing symptoms that lead to hospitalization; only 3% of patients discontinue this medicine because of flushing.

The flushing side effect can be greatly reduced by:

- Taking capsules with food reduced flushing by about 25%.
- Taking a small dose of non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes before taking Tecfidera.
   Aspirin reduces prostaglandin synthesis, which reduces flushing.

#### **Gastrointestinal Side Effects**

Tecfidera's gastrointestinal (GI) side effects include nausea, vomiting, diarrhea, abdominal pain, and dyspepsia). The amount of GI events was higher at the start of treatment (usually in month 1) and usually decreased over time in patients. Four percent (4%) of patients treated with Tecfidera and less than 1% of placebo patients discontinued due to gastrointestinal events in clinical trials

#### Serious Tecfidera side effects

Get emergency medical help if you have signs of an allergic reaction to this medication, such as hives, difficulty breathing, or swelling of your face, lips, tongue, or throat.

Dimethyl fumarate may cause a serious brain infection called progressive multifocal leukoencephalopathy (PML) that can lead to disability or death. Call your doctor right away if you have problems with speech, thought, vision, or muscle movement. These symptoms may start gradually and get worse quickly.

Also, call your doctor at once if you have:

- symptoms of herpes virus flu-like symptoms, cold sores around your mouth, tingly or painful blistering rash, burning pain in your thigh or lower back;
- low white blood cell counts fever, mouth sores, skin sores, sore throat, cough, trouble breathing, or
- liver problems loss of appetite, stomach pain (upper right side), tiredness, itching, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes).
- gastrointestinal problems, including bleeding, ulcers, blockage, and tears (perforation) of the stomach or intestines.
   Tell your healthcare provider right away if you have any of these symptoms during treatment: stomach-area pain that does not go away, bright red or black stools (that look like tar), severe vomiting, severe diarrhea, coughing up blood or blood clots, and vomiting blood or your vomit looks like "coffee grounds".

Also, see the Warning section.

This is not a complete list of side effects, and others may occur. Call your doctor for medical advice about side effects.

1 Tecfidera side effects (more detail)

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## **Warnings**

Before taking and while you take Tecfidera, tell your doctor if you have or have had a low white blood cell count or an infection.

This medicine may cause a serious viral infection of the brain that can lead to disability or death. Call your doctor right away if you have any change in your mental state, decreased vision, weakness on one side of your body, or problems with speech or walking. These symptoms may start gradually and get worse quickly.

## Before taking this medicine

You should not use Tecfidera if you have had a severe allergic reaction to dimethyl fumarate, diroximel fumarate (Vumerity), or any of the inactive ingredients contained in this medication.

To make sure this medication is safe for you, tell your doctor if you have ever had:

- an active infection; or
- low white blood cell (WBC) counts.

Tecfidera is not approved for use by anyone younger than 18 years old.

## **Pregnancy**

Tell your doctor if you are pregnant or plan to become pregnant, as it is not known if Tecfidera will harm your unborn baby. You and your doctor will have to decide if you should take this medicine while you are pregnant or if you plan to become pregnant. If you are pregnant, your name may be listed on a pregnancy registry to track the effects of dimethyl

fumarate on the baby.

### **Breastfeeding**

Tell your doctor if you are 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 this medicine or breastfeed.

Tecfidera pregnancy and breastfeeding warnings (more detail)

### How should I take Tecfidera?

Take Tecfidera exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose.

Your doctor will perform blood tests to make sure you do not have conditions that would prevent you from safely using this medication.

You may take Tecfidera with or without food. Taking the medicine with food may help prevent flushing (sudden warmth, redness, or tingly feeling).

Swallow the capsule whole, and do not crush, chew, break, or open it.

While using this medicine, you will need frequent blood tests.

Store this medicine in the original container at room temperature, away from moisture, heat, and light.

Tecfidera patient tips (more detail)

## **Tecfidera Dosing information**

**Usual Adult Dose for Multiple Sclerosis:** 

**Initial dose:** 120 mg orally twice a day for 7 days **Maintenance dose**: 240 mg orally twice a day

**Approved indication:** The treatment of adult patients with relapsing forms of multiple sclerosis, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

Detailed Tecfidera dosage information

# What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

## What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

### What to avoid

Follow your doctor's instructions about any restrictions on food, beverages, or activity.

## What other drugs will affect this medication?

Other drugs may interact with dimethyl fumarate, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all your current medicines and any medicine you start or stop using.

Click the link below to check for interactions with this medicine.

Tecfidera drug interactions (more detail)

### Does Tecfidera interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.



## Ingredients

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.

## **Storage**

- Store at 15°C to 30°C (59 to 86°F).
- Protect the capsules from light.
- Store in the original container.

## Company

Manufactured for: Biogen Inc., Cambridge, MA 02142.

## **Popular FAQ**

How do Vumerity and Tecfidera compare for multiple sclerosis (MS)?	~
Can I stop taking Tecfidera? What happens if I do?	~
What causes flushing with Tecfidera?	~
Can you drink alcohol while taking Tecfidera?	~
Gilenya vs Tecfidera. How do they compare?	~
How long can you take Tecfidera?	~
Can Tecfidera cause stomach damage?	~
Does Tecfidera cause weight gain or loss?	~

#### View more FAQ...

#### References

- 1. Fumarates modulate microglia activation through a novel HCAR2 signaling pathway and rescue synaptic dysregulation in inflamed CNS.
- 2. Insight into the mechanism of action of dimethyl fumarate in multiple sclerosis
- 3. Tecfidera Product Label FDA
- 4. Dimethyl Fumarate and Its Esters: A Drug with Broad Clinical Utility?

## More about Tecfidera (dimethyl fumarate)

- Check interactions
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- · Pricing & coupons
- Reviews (101)
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- Side effects
- Dosage information
- Patient tips
- During pregnancy
- · Generic availability
- Support group
- FDA approval history

- Drug class: selective immunosuppressants
- Breastfeeding
- En español

### **Professional resources**

- Tecfidera prescribing information
- Dimethyl Fumarate (AHFS Monograph)

### Related treatment guides

• Multiple Sclerosis

### **Further information**

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

#### **DRUG STATUS**

#### **Availability**

Rx Prescription only

#### **Pregnancy & Lactation**

ন্ত Risk data available

### CSA Schedule\*

N/A Not a controlled drug

### **Approval History**

10+ years FDA approved 2013

### **User Reviews & Ratings**

6.2 / 10

101 Reviews

#### **Images**

Tecfidera 240 mg (BG-12 240 mg)





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