

Tecfidera[®] (tek fi de rah)

Generic name: dimethyl fumarate (dī ME thəl, fyu MA rāt) or BG12

What is Tecfidera[®]?

Tecfidera[®] is a medication that easily enters the bloodstream when taken orally.

Tecfidera[®] slows the course of multiple sclerosis when used regularly over long periods of time. It does not improve existing symptoms and is not used to treat acute MS attacks.

Starting on Tecfidera[®].

To obtain Tecfidera[®], a form must be completed and faxed to the MS ActiveSource program. This program, operated by Biogen (the manufacturer of Tecfidera[®]), will start the process of obtaining the medication. MS Center staff will assist with completion of these forms and getting insurance approval. It takes about 10-14 days to get insurance approval. The medication is then shipped overnight to either your home or your pharmacy (depending on insurance requirements).

After the medication arrives, you can start taking the medication.

When first starting Tecfidera[®], it should be started at a low dose and tapered upwards. The 30 day starter pack comes with the first 7 days at a lower dose and days 8-30 at the full dose.

- Start with 120 mg twice a day for 7 days. These capsules are colored green on one end and white on the other end
- Starting on day 8, take 240mg twice a day. These capsules are green.
- Flushing and gastrointestinal side effect can occur when the medication is first started (see below for details). These side effects can be helped by taking aspirin before each dose and taking each dose with food.
 - First, take one adult aspirin. Non-aspirin products will **not** work (acetaminophen, Tylenol[®], ibuprofen, Motrin[®], naproxen, Advil[®])
 - Then eat a meal. The Tecfidera[®] is taken twice a day, so this would be breakfast or dinner.
 - Then take the Tecfidera[®] after the meal.

How should Tecfidera[®] be taken?

Tecfidera[®] is taken orally. Swallow the capsule whole; do not chew or crush the capsule.

Frequency: twice a day

Laboratory tests should be done to check for blood counts prior to starting the medication. It is recommended that annual blood counts be checked out the medication, but our Center usually checks blood tests about every three months during the first year with lesser frequencies after that.

Multiple Sclerosis Center

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www.swedish.org/ms or
www.swedishmscenter.org

What if a dose is missed?

Take the next dose as soon as you can after remembering. Doses should be given about 12 hours apart.

How should Tecfidera® be stored? Tecfidera® should be stored at room temperature. Avoid excessive humidity because it can dissolve the capsule.

How supplied: Tecfidera® comes in two sizes, 120mg and 240mg capsules. The 120mg capsule is used to start the medication at a lower dose. The 240mg capsule is the standard dose.

What are the common side effects?

- Flushing: About 40% of people have this symptom. This occurs about 15-20 minutes after taking a dose. It is a feeling of warmth and redness, especially over the upper body and face. It may have prickling or tingling over the face. This symptom usually improves over a few months. Flushing can be minimized by:
 - Taking one adult aspirin before each dose. Non-aspirin products will not work.
 - Taking the Tecfidera® on a full stomach, usually after breakfast and dinner.
 - Take the aspirin first, then eat a meal, then take the Tecfidera® after the meal..
- Gastrointestinal symptoms: About 20% of people have these symptoms. This symptom usually gets better in a month or less after starting the medication. Gastrointestinal symptoms may include nausea, vomiting, diarrhea, gas, bloating or abdominal pain, Gastrointestinal symptoms can be minimized by:
 - Taking the Tecfidera® after a meal.
 - Other medications may be given to counteract these symptoms until your body adjusts to the medication.
- Low white blood counts: Tecfidera® may cause a decrease in the lymphocytes, which are one type of white blood cells. This is usually mild and not medically important. However, about 6% of patients may have a decrease low enough to be concerning. Because of this, blood tests to monitor this are needed before starting Tecfidera®. It is recommended that annual blood tests be done to monitor this side effect, but our clinic typically checks blood tests every 3 months for the first year.
- Liver injury. Rarely, liver injury may occur. This has been mild and it is **not** necessary to follow this with testing.
- Progressive multifocal leukoencephalopathy (PML): PML has occurred in some patients treated with a related compound available in Europe for the treatment of psoriasis. This has **not** been seen with Tecfidera®. All of the cases seen with this related compound have occurred in patients with severe decreases in blood counts. We monitor blood counts on Tecfidera® for this reason.

Company Support:

MS ActiveSource 1-800-456-2255 Provides financial assistance, insurance assistance, information about Tecfidera® and multiple sclerosis.

www.Tecfidera.com

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