**Tecfidera®** (TEK fi DE rah)
Generic name: dimethyl fumarate (dī METH ul, FEW mar āte)

**What is Tecfidera®?**

Tecfidera® is an oral medication that easily enters the bloodstream. Tecfidera® activates the body’s antioxidant pathways. It also decreases the activity of certain white blood cells that are believed to be responsible for the immune attack on the nervous system in multiple sclerosis.

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®

1. A start form must be completed and faxed to the AboveMS program. This program, operated by Biogen, the manufacturer of Tecfidera®, will start the process of obtaining the medication. Pharmacotherapy clinic staff can assist with completion of these forms and getting insurance approval. It takes 1-2 weeks to get insurance approval. Sometimes, insurance denials and appeals may take longer.

2. Insurance often pays only part of the cost of Tecfidera®. The contract between the patient and the insurance company specifies the amount of deductibles and copayments.
   - The deductible is the amount patients must pay each year before their insurance starts covering costs.
   - The copayment is the amount patients must pay for each medical bill.

For medications, the copayment is often a percent of the medication’s cost. Pharmacotherapy clinic staff can assist in getting the manufacturer or foundations to decrease the cost of deductibles and copayments.

3. The medication is not stocked in your pharmacy. It must be shipped overnight from a distributor to either your home or your pharmacy (depending on insurance requirements). Pharmacotherapy clinic staff can assist in the shipping process.

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.

- **Week 1:** take one 120 mg capsule after dinner each day for 7 days. These capsules are colored green on one end and white on the other end.
- **Week 2:** take one 240 mg capsule after dinner each day for 7 days. These capsules are green.
- **Week 3:** take one 120 mg capsule after breakfast and one 240 mg capsule after dinner.
- **Week 4 and after:** take one 240 mg capsule twice a day, one after breakfast and one after dinner.
Some patients starting Tecfidera may experience flushing (a sense of warmth, associated with redness of the skin of your face, neck and upper chest) and gastrointestinal side effects (indigestion, cramping, gas or diarrhea).

- **Flushing** can be reduced by
  - Taking each dose of Tecfidera® after a meal. Fatty or protein-rich foods are particularly helpful (a tablespoon of peanut butter or an avocado).
  - If this does not help, try aspirin unless you are allergic to aspirin, are on a blood thinner, or have experienced gastric ulcers/bleeding. Take a single tablet of aspirin (81 mg or 325 mg) before the meal, then eat, then take the Tecfidera®. Use non-coated aspirin, or crush coated aspirin before taking it. Non-aspirin products will **not** work (acetaminophen, Tylenol®, ibuprofen, Motrin®, naproxen, Advil®).

- **Gastrointestinal side effects** can be reduced by
  - Taking each dose of Tecfidera® after a meal.
  - If this does not help, try over-the-counter remedies (e.g. Prilosec for indigestion)
  - If this does not help, contact our office for additional suggestions. Prescription medications such as Singulair (montelukast) may be helpful.

**Safety Monitoring**
- Blood tests (CBC+differential, liver function tests) should be done to check for blood counts prior to starting the medication. Our Center usually checks blood tests every three months during the first 2 years with lesser frequencies after that.

**How should Tecfidera® be taken?**
Tecfidera® is taken orally. Swallow the capsule whole; do not chew or crush the capsule.
- Frequency: twice a day

**What if a dose is missed?**
If you are less than 4 hours late, take the next dose immediately. If you are more than 4 hours late, wait and take your next dose at the usual time. 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. Methods to minimize flushing are described above.

- **Gastrointestinal symptoms:** About 20% of people have these symptoms. Gastrointestinal symptoms may include nausea, vomiting, diarrhea, gas, bloating or abdominal pain. This symptom usually gets better in 6-8 weeks after starting the medication. Methods to minimize flushing are described above.

- **Low white blood counts:** Tecfidera® may decrease in the number of lymphocytes, which is a type of white blood cell. About 6% of patients may have a decrease low enough to be concerning. Blood tests are needed to monitor this.

What are the rare side effects?

- **Liver injury.** Rarely, liver injury may occur. Liver function tests (via blood draw) are needed to monitor this.

- **Progressive multifocal leukoencephalopathy (PML):** PML is a virus infection of the brain and is described in more detail on our website. PML occurs in approximately 1 in 65,000 patients treated with Tecfidera®. For comparison, the risk of getting struck by lightning in the US is approximately 1 in 12,000. The risk of PML is higher in patients with severe decreases in white blood counts. We monitor white blood counts in patients on Tecfidera® for this reason.

Company Support:
Above MS: 1-800-456-2255 Provides financial assistance, insurance assistance, information about Tecfidera® and multiple sclerosis.
www.Tecfidera.com