



TecfideraTM
(dimethyl fumarate)

Produced by Lind Publishing, Inc.



MS Treatments

MSology Essentials Series

Tecfidera™

(dimethyl fumarate)

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Why treat MS?

Multiple sclerosis (MS) is believed to be caused by an abnormal immune response, which results in inflammation and tissue damage in the brain and spinal cord (together called the central nervous system, or CNS). This inflammation is the cause of MS symptoms, such as nerve tingling, muscle weakness, vision problems, balance difficulties and pain. New or worsening MS symptoms that last for more than a day or two are called relapses, and these generally indicate an inflammatory flare-up in the CNS. Relapse symptoms can persist for several weeks or months. Some relapses will resolve completely and some will not. As you experience more and more relapses, the body is unable to repair the damage to the brain and spinal cord, which typically leads to physical and mental impairments.

That is why it is so important to treat MS – to reduce inflammation and tissue damage, and reduce or delay disability. The medications prescribed are called disease-modifying therapies because they target the underlying MS disease process. They do not heal any tissue damage that has already occurred, but they may prevent further damage that will contribute to disability in the years ahead.

MS medications do not treat specific symptoms, so you will not feel an improvement in the symptoms you are having. The main effects of therapy are to lessen the frequency and severity of relapses, and reduce the amount of inflammation in the brain and spinal cord. So treatment can be seen as an investment in your future – lessening the often silent damage that is occurring now to prevent disabilities later on.



How does Tecfidera work?

Tecfidera is an oral medication (capsule) used to treat relapsing-remitting multiple sclerosis.

In MS, specialized cells of the immune system become activated, enter the CNS and cause inflammation and tissue damage. Tecfidera has anti-inflammatory effects and may activate the body's antioxidant response, although how it works in MS is not known.

Clinical trials of Tecfidera have shown that it reduces the rate of relapses, delays the onset of worsening disability, and suppresses inflammatory lesions in the brain in people with MS.



Starting with a lower dose of Tecfidera in the first week (120 mg twice a day) allows your body to get used to the medication and may help to reduce side effects. But it is very important that you increase the dose (to 240 mg twice a day) when your doctor instructs you to do so.

If you have problems with side effects, talk to your MS nurse, pharmacist or Biogen ONE™ nurse. They have many tips that can make it easier to take your medication.



How do I take Tecfidera?

Dosing

Tecfidera must be taken twice a day.

Tecfidera comes in capsules of 120 or 240 mg, to be taken by mouth, without chewing.

2x
a day

The initial dose of Tecfidera is one 120-mg capsule twice-daily. This means you will be taking a total of 240 mg each day. The lower dose should be taken for 1 week. (Your doctor may suggest you continue taking this dose for a longer period).


120 mg

The dose used to treat MS is one 240-mg capsule taken twice-daily. This means you will be taking a total of 480 mg each day. Your doctor will advise you when need to start gradually increasing to this higher dose. The full dose (240 mg taken twice-daily) is needed to control your MS.


240 mg

Considerations

Try to get into a routine of taking your medication at the same times each day, such as with breakfast and with your evening meal. If you forget a dose (e.g. at breakfast), take it at least 4 hours before (e.g. at lunch) the next scheduled dose (e.g. at dinner).



It is generally recommended that you take Tecfidera with food, such as a meal that contains some fats and proteins.





How do I know my treatment is working?

During your course of treatment, your doctor will monitor your response to treatment with a variety of tests and procedures. These typically include neurological examinations to evaluate your nerve and muscle function, and magnetic resonance imaging (MRI) to assess the extent of inflammatory activity in your brain and spinal cord. Other tests and procedures may also be needed during your course of treatment.

What if I have a relapse?

A *relapse* is a new MS symptom you haven't had before, or a worsening of symptoms you've previously experienced. The symptom persists for at least 24 hours. If you become overheated – from exercise, a hot bath, a fever or infection – your MS can worsen for a shorter period of time, but these symptoms are not a true relapse.

You may have a relapse in the first few months after starting treatment, especially if your MS was very active before. This doesn't mean your medication is not working. You will only experience the full benefit of your MS medication after you've been taking it continuously for a few months.

It's important to inform your neurologist or MS nurse if you experience a relapse or any new or worsening symptoms that last more than 24 hours.



What are the possible side effects of Tecfidera ?

Stomach upset

This can include nausea, vomiting, stomach cramps, diarrhea, heartburn or digestive problems.

Flushing

You may experience a sensation of warmth, itching or burning after taking Tecfidera. This effect may become less troublesome after you've been taking Tecfidera for several weeks. If flushing is a problem, try taking an uncoated Aspirin (ASA) just before you take Tecfidera. Ask your doctor or MS nurse about the dose of Aspirin that is right for you and how long you can take it.

Effects on the liver

Tecfidera can have an effect on liver function so regular blood tests will be needed.

Effects on the kidney

Tecfidera may affect kidney function so periodic urine tests will be needed.

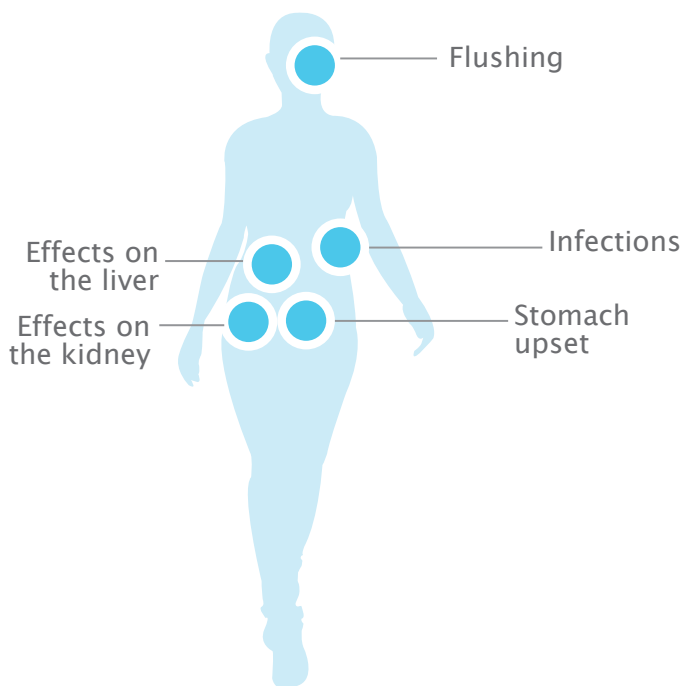
Infections

Tecfidera may increase your risk of infections. Report any signs of infection to your family doctor, neurologist or MS nurse.



PML

One case of PML (progressive multifocal leukoencephalopathy), a potentially fatal brain infection, has been reported with Tecfidera. The risk of PML is considered to be very low. A risk factor may be persistently low blood cell counts, which can occur with Tecfidera, so your doctor will order blood tests periodically during your course of treatment.



All medications have the potential to cause a variety of side effects. If you experience any new, unusual or worrisome symptoms while taking your medication, report them promptly to your doctor or MS nurse. Your MS nurse can often provide helpful advice to minimize any unwanted medication-related effects you may experience.



Hypersensitivity reactions

These are very rare but can occur with Tecfidera. If you experience severe flushing, breathing difficulties or swelling of the face, lips or tongue, seek medical attention immediately.

Tests and procedures

During your course of treatment, your doctor will order a number of tests to ensure that your medication is not causing any unwanted effects. Some of the suggested tests are listed in the table. However, your neurologist and MS nurse will schedule which tests you will need and how often they should be done.

The tests you may need during treatment with Tecfidera*

Test/procedure	Reason	How often
Blood test	To determine your complete blood cell count (CBC) The blood test will also be used to examine your liver function	<ul style="list-style-type: none">• Before starting Tecfidera• After 6 months of treatment, then every 6–12 months thereafter• If you develop an infection during treatment
Urine sample	To see if there are proteins in the urine	<ul style="list-style-type: none">• Before starting Tecfidera• After 6 months of treatment, then every 6–12 months thereafter

* Your neurologist or MS nurse will tell you more about the testing you'll need during treatment. Please ensure that you have all of the necessary tests at the recommended times.



Pregnancy

It's generally advisable to avoid taking medications during pregnancy because they may cause harm to the developing fetus. The best approach is to talk to your doctor or MS nurse before becoming pregnant so you can work out a schedule for stopping and re-starting your medication.



Tecfidera should not be taken during pregnancy or breastfeeding



Women should use a reliable method of contraception during treatment. Tecfidera may reduce the effectiveness of oral contraceptives, so another method of birth control should be considered.

Call your MS nurse or neurologist if you are planning a pregnancy or if you are pregnant. You'll need to discuss interrupting your treatment until after the baby is born. It's generally best to resume treatment after you have stopped breastfeeding.



Always use a reliable method of contraception while taking an MS medication. Talk to your doctor or MS nurse if you are planning a pregnancy in the next few months.



Other medications

All medications have the potential to interact with other drugs you are taking. This includes other prescription medications, as well as non-prescription drugs and alternative/complementary therapies. Some of these medications can also worsen MS symptoms.

Talk to a healthcare professional before taking any medication. Your doctor, MS nurse or pharmacist can advise you about interactions that may occur with Tecfidera and the other medications you are taking.

Other medical conditions

Always ensure that your doctor is aware of any other medical conditions you may have. This includes high blood pressure, liver problems, diabetes, infections, or other illnesses.

Resources in your community

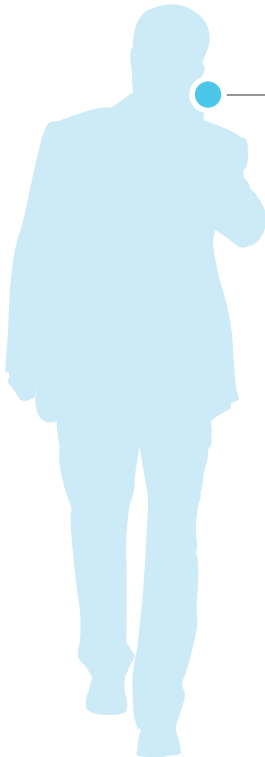
Your neurologist or MS nurse will talk to you about the Biogen ONE™ Patient Services Program, which provides information and support for people taking Tecfidera.

Your local pharmacist can also provide important advice on your medication, how to take it, and what other medications (including non-prescription and alternative/complementary therapies) to avoid.



Contacting your MS nurse

Contact your MS nurse if you have any questions or concerns about your medication. It is important to notify your doctor or MS nurse if you have any new, worrisome or unusual symptoms that may be related to your medication, or any worsening of your MS symptoms.




Notify your doctor or MS nurse if you have any new symptoms



The MS Essentials series provides the latest information on multiple sclerosis medications, research, and lifestyle issues such as health, nutrition and exercise. All of the booklets are developed by Lind Publishing, publishers of MSology, to help people affected by MS remain active and informed. MS Essentials is provided free of charge. The full series of publications is available for download on <http://www.MSology.com>.

The information reflects use of the medication in Canada; use may vary in other countries. MSology does not approve, endorse or recommend any specific product or therapy. Contact your healthcare providers before you start treatment, alter the dose, interrupt or discontinue your therapy. For full information about a specific medication, consult the prescribing information or package insert provided by the manufacturer for your country.





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For more multiple sclerosis information, visit www.MSology.com

