



Tecfidera™, a New Oral medication for MS is approved by FDA!

A third oral medication, dimethyl fumarate (Tecfidera™) was approved by FDA on 3/27/2013 for the treatment of relapsing forms of multiple sclerosis. This medication was known in clinical trials as “BG-12”. **Tecfidera™ is the tenth disease-modifying therapy available** for the treatment of MS, and the **third after fingolimod (Gilenya®) and teriflunomide (Aubagio®) that is taken by mouth.** Tecfidera™ is a pill given twice per day. The full dose is 240 mg taken twice daily, once in the morning and once in the evening.

How does dimethyl fumarate (Tecfidera™) work?

MS is believed to be an autoimmune process where cells from the immune system, T lymphocytes and B lymphocytes, produce inflammation and damage of the white matter and nerve cells in different parts of the brain and spinal cord. While the exact mechanism of action is not known, research indicates that Tecfidera™ works by inducing the immune system to be less inflammatory. This is accomplished by the drug inducing a shift in the type of lymphocytes that are activated and by decreasing the numbers of circulating T lymphocytes. In addition, Tecfidera™ may inhibit certain molecules that are involved in the inflammatory process. Tecfidera™ may also activate a pathway that can reduce damage to myelin and nerves

How was dimethyl fumarate (Tecfidera™) tested in MS?

Two large clinical trials were conducted to test the effectiveness and safety of Tecfidera™. The first study, known as DEFINE was a 2-year randomized, double-blind, placebo-controlled study in 1234 patients with relapsing-remitting forms of MS (RRMS). Patients were randomized to receive Tecfidera™ 240 mg twice a day, Tecfidera™ 240 mg three times a day, or placebo for up to 2 years. The results in the two Tecfidera™ groups were similar. The results indicated a 53% reduction in annualized relapse rate in the twice daily Tecfidera™ group relative to placebo. Risk of progression was reduced by 38% relative to placebo. Assessment of MRI outcomes showed fewer new or enlarging lesions and fewer gadolinium enhancing lesions.

The second trial, known as CONFIRM, was a 2 year trial with 1417 participants, randomized to one of the following groups: Tecfidera™ 240 mg twice daily, Tecfidera™ 240 mg three times/day, Copaxone 20 mg daily injections or placebo. The results indicated a 44% reduction in annual relapse rate in the twice daily Tecfidera™ group relative to placebo. There was no effect demonstrated on progression in this trial. The twice daily Tecfidera™ group demonstrated a significant effect on the MRI outcomes with fewer new or enlarging lesions and few gadolinium enhancing lesions.

How is dimethyl fumarate (Tecfidera™) administered?

The **starting dose** for Tecfidera™ is 120 mg twice a day. After 7 days, the dose should be increased to the full dose of 240 mg twice a day. Tecfidera™ can be taken with or without food.

How does dimethyl fumarate (Tecfidera™) compare with other medications for MS?

Tecfidera™ has not been tested in a head-to-head trial against other MS medications. In the CONFIRM trial there was a group assigned to receive Copaxone, however, the study was not done to compare the effectiveness of one drug against the other.

What are the side effects of dimethyl fumarate (Tecfidera™)?

As with other medications used in MS, Tecfidera™ may cause side effects. These include gastrointestinal (GI) symptoms such as abdominal pain (18% of trial participants), diarrhea (14% of trial participants), nausea (12% of trial participants), vomiting (9% of trial participants), bloating, and skin-related manifestations such as flushing (40% of trial participants). There was also elevation in liver enzymes and lowering of lymphocyte count (white blood cells) in some patients but the rate of infections was no different as compared with patients taking placebo. This drug has *Pregnancy category “C”* which means that it may be unsafe for use during pregnancy. In addition, it is not recommended for use while breast feeding.

Is there any need for monitoring, such as blood tests, while on treatment with dimethyl fumarate (Tecfidera™)?

There is need for initial monitoring of liver function tests and lymphocyte counts in patients receiving Tecfidera™.

Which patients can receive dimethyl fumarate (Tecfidera™)? Or Which patients can switch from the current injectables to dimethyl fumarate (Tecfidera™)?

Tecfidera™ was tested in patients with relapsing multiple sclerosis. In this type of MS, new symptoms that develop and last at least 24 hours and are in the absence of a fever or other metabolic cause are called relapses or exacerbations. Symptoms will usually persist for a few weeks or even months. Recovery may be 100% or sometimes less than 100%. There is usually a period of clinical stability (remission) in between episodes (relapses).

Tecfidera™ has not been tested in patients with secondary-progressive or primary-progressive MS in any large clinical trials.

Tecfidera™ is indicated for relapsing MS. If you are interested in knowing if Tecfidera™ is right for you, please discuss this with your MS provider.

For more information about Tecfidera™ please go to the Tecfidera™ website: Tecfidera.com or call: *MS ActiveSource* at 1-800-456-2255; Monday - Friday, 8:30 AM-8:00 PM (ET)