

>385,000

people have been treated with TECFIDERA worldwide^{2*}

>710,000

global patient-years of experience^{2*}

>11 years

of combined clinical trial and real-world experience^{1,2}

#1

oral R since

*This includes clinical trial use and patients prescribed TECFIDERA.

[†]As of March prescription



TECFIDERA efficacy across 2 pivotal trials and additional studies^{1,4-8}

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Data on newly diagnosed patients at 2 and 6 years^{7,8}

[Explore these analyses >](#)



Well-known safety across 2 pivotal trials^{1,4,5}

[Explore safety >](#)

IMPORTANT SAFETY INFORMATION AND INDICATION

†Coverage may vary, and there is no guarantee of coverage.

DEFINE=Determination of the Efficacy and Safety of Oral Fumarate in Relapsing-Remitting MS⁴; CONFIRM=Comparator and an Oral Fumarate in Relapsing-Remitting Multiple Sclerosis.⁵

References: 1. TECFIDERA Prescribing Information, Biogen, Cambridge, MA. 2. Biogen, Data on file. 3. IMS NPA™. Number of prescription drugs (2013-March 29, 2019). 4. Gold R, et al. *N Engl J Med.* 2012;367(12):1098-1107. Erratum in: *N Engl J Med.* 2012;367(24):2362. 5. Fox RJ, et al. *N Engl J Med.* 2012;367(17):1673. 6. Gold R, et al. *Mult Scler.* 2017;23(2):253-265. 7. Gold R, et al. *Mult Scler.* 2015;21(1):45-47.

IMPORTANT SAFETY INFORMATION

TECFIDERA® (dimethyl fumarate) is contraindicated in patients with known hypersensitivity to dimethyl fumarate or any of its components. TECFIDERA can cause anaphylaxis and angioedema after the first dose or at any time during treatment. Patients experiencing symptoms of anaphylaxis and angioedema (which have included difficulty breathing, urticaria, and swelling of the throat and tongue) should discontinue TECFIDERA immediately and seek immediate medical care.

Progressive multifocal leukoencephalopathy (PML) has occurred in patients with MS treated with TECFIDERA. PML is a rare, potentially fatal brain disease caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that can lead to significant disability. A fatal case of PML occurred in a patient who received TECFIDERA in a clinical trial. PML has also occurred in patients with the presence of lymphopenia ($<0.8 \times 10^9/L$) persisting for more than 6 months. While the role of lymphopenia in these cases is unclear, PML occurred in patients with lymphocyte counts $<0.5 \times 10^9/L$. The symptoms associated with PML are diverse, progress over time, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, confusion and personality changes. At the first sign or symptom suggestive of PML, withhold TECFIDERA and perform a neurological evaluation. MRI findings may be apparent before clinical signs or symptoms.

TECFIDERA may decrease lymphocyte counts; in clinical trials there was a mean decrease of ~30% in lymphocyte counts. Lymphocyte counts remained stable. Four weeks after stopping TECFIDERA, mean lymphocyte counts increased but not to baseline. Six weeks after stopping TECFIDERA, $<1\%$ of placebo patients had lymphocyte counts $<0.5 \times 10^9/L$. TECFIDERA has not been studied in patients with pre-existing lymphopenia.

There was no increased incidence of serious infections observed in patients with lymphocyte counts $<0.8 \times 10^9/L$ or $\leq 0.5 \times 10^9/L$, although one patient in an extension study developed PML in the setting of prolonged lymphopenia (lymphocyte counts $<0.5 \times 10^9/L$ for at least 6 years). In controlled and uncontrolled clinical trials, 2% of patients experienced lymphocyte counts $<0.5 \times 10^9/L$ for at least 6 months. The majority of lymphocyte counts remained $<0.5 \times 10^9/L$ with continued therapy. A complete blood count including lymphocyte counts should be obtained before initiating treatment, 6 months after starting, every 6 to 12 months thereafter and as clinically indicated. Consider discontinuing TECFIDERA if lymphocyte counts $<0.5 \times 10^9/L$ persist for more than six months and follow lymphocyte counts until lymphopenia is resolved. Discontinue treatment in patients with serious infections until resolved. Decisions about whether or not to restart TECFIDERA should be made on an individual basis under the following circumstances.

Clinically significant cases of liver injury have been reported in patients treated with TECFIDERA in the postmarketing period. Liver injury occurred a few days to several months after initiation of treatment. Signs and symptoms of liver injury, including elevation of serum aminotransferase levels greater than 5-fold the upper limit of normal and elevation of total bilirubin to greater than 2-fold the upper limit of normal have been reported. Most abnormalities resolved upon treatment discontinuation. Some cases required hospitalization. None of the reported cases resulted in liver transplant, or death. However, the combination of new serum aminotransferase elevations with increased levels of bilirubin is a sign of hepatocellular injury is an important predictor of serious liver injury that may lead to acute liver failure, liver transplant, or death.

Elevations of hepatic transaminases (most no greater than 3 times the upper limit of normal) were observed during clinical trials. Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels before initiating TECFIDERA and during treatment. Discontinue TECFIDERA if liver injury is suspected. Do not restart TECFIDERA if liver injury is suspected.

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IMPORTANT SAFETY INFORMATION AND INDICATION