

Dimethyl fumarate: Drug information

Brand Names: US

Tecfidera

Brand Names: Canada

Tecfidera

Pharmacologic Category

Fumaric Acid Derivative; Immunomodulator, Systemic

Mechanism of Action

DMF and its active metabolite, monomethyl fumarate (MMF), activate the nuclear factor (erythroid-derived 2)-like 2 (Nrf2) pathway, which is involved in cellular response to oxidative stress. The mechanism by which dimethyl fumarate (DMF) exerts a therapeutic effect in MS is unknown; it is believed to result from its anti-inflammatory and cytoprotective properties via activation of the Nrf2 pathway.

Pricing: US

Capsule, delayed release (Tecfidera Oral)

120 mg (per each): \$147.32; 240 mg (per each): \$147.31

Pricing: Brasil

Capsule, delayed release (Tecfidera Oral)

120 mg (per each): R\$ 125,89

240 mg (per each): R\$ 125,89

Dosage Forms

Capsule Delayed Release, Oral:

Tecfidera: 120 mg and 240mg

Generic Equivalent Available (US): No

Use: Multiple sclerosis: Treatment of patients with relapsing forms of multiple sclerosis

Dosing: Adult

Multiple sclerosis (relapsing): Oral: Initial: 120 mg twice daily; after 7 days, increase to the maintenance dose: 240 mg twice daily.

Dosing: Renal Impairment: Adult

No dosage adjustment necessary.

Dosing: Hepatic Impairment: Adult

No dosage adjustment necessary.

Contraindications

Known hypersensitivity (eg, anaphylaxis, angioedema) to dimethyl fumarate or any component of the formulation

Dosing: Adjustment for Toxicity

Flushing, GI intolerance, or intolerance to maintenance dose: Consider temporary dose reduction to 120 mg twice daily (resume recommended maintenance dose of 240 mg twice daily within 4 weeks). Consider discontinuation in patients who cannot tolerate return to the maintenance dose.

Hepatic injury (suspected drug-induced), clinically significant: Discontinue treatment.

Lymphocyte count $<500/\text{mm}^3$ persisting for >6 months: Consider treatment interruption.

Administration

Oral: Swallow capsules whole and intact; do not crush, chew, open the capsule, or sprinkle contents on food. Administer with or without food; administering with high-fat, high-protein food (eg, yogurt or peanut butter) may decrease the incidence of flushing and gastrointestinal effects (Mayer 2017). Administration of aspirin (nonenteric coated up to a dose of 325 mg) 30 minutes prior to dimethyl fumarate may also reduce the incidence of flushing.

Monitoring Parameters

CBC including lymphocyte counts (obtained prior to initiation of therapy, then every 3 months thereafter and as clinically necessary; grade 3 lymphopenia should be monitored more frequently at intervals <3 months) (AAN [Rae-Grant 2018]); liver function tests (transaminases, alkaline phosphatase, total bilirubin) prior to treatment initiation and during treatment as clinically indicated; urinalysis (if proteinuria suspected and/or clinically indicated). Monitor for signs/symptoms of hypersensitivity, infections, and/or progressive multifocal leukoencephalopathy (PML).