BAFIERTAM®: It's Monomethyl Fumarate, Pure & Simple

More than 560,000 patients representing more than 1.1 million patient years have been exposed to monomethyl fumarate (MMF) for the treatment of MS*

Bafiertam®
(monomethyl fumarate) delayed-release capsules 95mg

Indication, Usage, and Select Important Safety Information

BAFIERTAM is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Contraindications

BAFIERTAM is contraindicated in patients

- With known hypersensitivity to monomethyl fumarate, dimethyl fumarate, diroximel fumarate, or to any of the excipients of BAFIERTAM. Reactions may include anaphylaxis or angioedema.
- Taking dimethyl fumarate or diroximel fumarate.

Please see Important Safety Information on page 8 and the full Prescribing Information.

*Biogen, News, April 4, 2022.

A Proven Effective Agent in the Long-Trusted Fumarate Class

Over 2 years, studies have shown that the active MMF molecule of BAFIERTAM reduces*:

Annualized relapse rate (ARR) in patients after 2 years by **44-53%**

T1 hypointense lesion development by **57-73%**

Disability progression by **21-38%†**

T2 lesion development by **71-85%**

*Based on studies conducted with DMF by Biogen Inc.

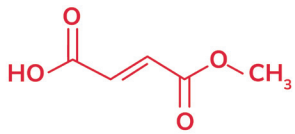
†Disability progression was defined as at least a 1-point increase from baseline EDSS (1.5-point increase for patients with baseline EDSS of 0) sustained for 12 weeks.

Choose BAFIERTAM for Direct Delivery of MMF, Without Enzymatic Conversion

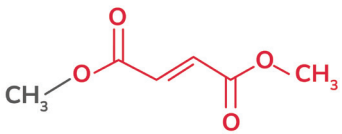
BAFIERTAM, a branded product, is unique in its class.

Where the prodrugs dimethyl fumarate (DMF) and diroximel fumarate (DRF) are metabolized to produce the active metabolite MMF, BAFIERTAM does not require gastrointestinal conversion to deliver this active agent directly into systemic circulation. As a result, byproducts like hydroxyethyl succinimide (HES) are avoided.[1-3]

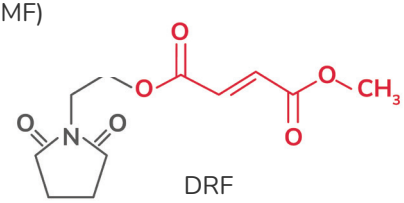
Three Oral Fumarates, All Built on MMF



BAFIERTAM (MMF)



DMF



DRF

How does MMF work?

MMF activates the Nrf2 pathway by promoting the release of Nrf2, allowing it to translocate to the nucleus and upregulate the antioxidant and cytoprotective genes. This mechanism reduces oxidative stress and inflammation thereby helping to protect neurons and the progression of MS.[4]

View Efficacy Data BAFIERTAMhcp.com/treatment-efficacy

1. Palte MJ, et al. *Adv Ther.* 2019;36(11):3154-3165. **2.** Lategan TW, et al. *CNS Drugs.* 2021;35:567-574. **3.** Wynn D, et al. *Mult Scler Relat Disord.* 2020;45:102335. **4.** Ahuja et al. (2016) https://doi.org/101523/JNEUROSCI.0426-16-2016.

Please see Important Safety Information on page 8 and the full Prescribing Information.

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Start or Switch: Who's Right for BAFIERTAM?

BAFIERTAM is ideal for patients who:

- Would benefit from a fumarate
- Are planning to start a family or may become pregnant
- Need an easy-on/easy-off therapy that's eliminated within 24 hours
- May require initial or ongoing screening for cardiac, hepatic, ophthalmic, or renal function
- May be taking other medications
- Prefer an oral treatment over injections or infusions

BAFIERTAM requires simple blood tests to start therapy and about every 6 months to continue treatment.

BAFIERTAM® has no dietary restrictions. Unlike prodrugs, whose pharmacokinetics—and therefore efficacy and safety—may be affected by food and alcohol consumption, or renal function:

- A high-fat, high-calorie meal does not significantly affect MMF plasma exposure*
- No need to count calories, restrict diet, or change eating or drinking habits
- Can be taken with or without food

MMF is eliminated quickly, making it straightforward to manage adverse events or discontinue in the event of pregnancy. Byproducts of prodrugs may add complexity for use.

*A high-fat, high-calorie meal did not significantly affect the overall MMF plasma exposure (AUC/area under the curve) but decreased the C^{max}/peak concentration of MMF by 20% with prolonged absorption. The median T^{max}/time of maximum concentration observed of MMF was delayed from approximately 4 hours to 11 hours by a high-fat meal.

More Flexible Dosing, Easier to Take

The smaller size of BAFIERTAM delivers MMF in an efficient dose for direct therapeutic effect.

BAFIERTAM is dosed as **two 95-mg, easy-to-swallow, soft-gel capsules twice daily**. Dispensed in a single bottle, this allows for flexible titration without compromising efficacy, so a specific starter pack is not required for initiation or dose adjustments.

BAFIERTAM (MMF)

190 mg twice daily[1]

Pills are shown to scale but not actual size

Other fumarates (DMF/DRF)

240 mg for DMF and 462 mg for DRF twice daily[2,3]

Common Adverse Events

MMF is the simplest fumarate molecule with a well-understood safety profile. Flushing and stomach upset are the most common problems, especially at the start of treatment, and may decrease in severity over time.

Tip: Prophylactic use of nonenteric-coated aspirin 30 minutes before taking BAFIERTAM may limit flushing symptoms.

Tip: Taking BAFIERTAM without food may ease or relieve gastrointestinal symptoms.

View Safety Data BAFIERTAMhcp.com/safety-profile

1. BAFIERTAM. Prescribing Information. Banner Life Sciences LLC; 2021. **2.** TECFIDERA. Prescribing Information. Biogen Inc; 2022. **3.** VUMERITY. Prescribing Information. Biogen Inc; 2022.

Please see Important Safety Information on page 8 and the full Prescribing Information.

Bafiertam® (monomethyl fumarate) delayed-release capsules 95mg

Simplifying Patient Access, Coverage, & Support Is Our Priority

Banner Life Sciences® offers the support you need to get your patients on therapy quickly—and to help patients continue BAFIERTAM treatment without interruption.

- Dedicated care managers offer personalized support to both patients and office staff
- Insurance benefit verification to help determine patient-specific coverage requirements
  - **QuickStart Program:** When coverage is delayed, a 30-day supply of BAFIERTAM is provided at no charge while benefits are verified
  - **Bridge Support Program:** Helps avoid therapy interruption due to coverage changes or delays, providing up to 12 months* of BAFIERTAM until coverage is secured
- **$0 Copay Program** provides financial assistance to eligible patients who sign up for the BAFIERTAM Savings Card†
- Easy access to BAFIERTAM from specialty pharmacies

*Banner Life Sciences reserves the right to modify this program at any time without notice. Other limitations may apply.

†The $0 Copay Program is subject to an annual cap on the amount of assistance patients can receive. This offer is invalid for patients covered by any governmental program, including, without limitation, Medicaid, Medicare, VA, or TRICARE. Federal and state laws and other factors may prevent or otherwise restrict eligibility.

Questions? Call Banner Support
1-855-3BANNER (1-855-322-6637)

Monday through Friday
(8:30 AM to 8:00 PM ET)

Prescribing BAFIERTAM Is Simple for You and Your Patients

You can e-prescribe BAFIERTAM using your preferred platform.


Bafiertam (monomethyl fumarate) delayed-release capsules 95mg

Patient Enrollment Form

Please complete form and fax toll-free
FAX: 1-866-539-0270

PATIENT INFORMATION

PATIENT AUTHORIZATION
I have read and agree to the Patient Authorization (page 2).

INSURANCE INFORMATION (PLEASE PROVIDE COPIES OF FRONT AND BACK OF ALL MEDICAL AND PRESCRIPTION INSURANCE CARDS)

HEALTHCARE PROVIDER (HCP) INFORMATION

DIAGNOSIS AND PRESCRIPTION (SIGNATURE STAMPS NOT ACCEPTABLE)

Titration Dose for Bafiertam 95mg caps:
95 mg PO BID x 7 days then increase to 190mg (95 mg x 2 capsules) PO BID
Qty: #120 capsules Refills: No refills

Quick Start Program:
Eligible patients can receive their first month's supply at no cost

Maintenance Dose for Bafiertam 95mg caps:
190 mg (95 mg x 2 capsules) PO BID
Qty: ☐ 60-day supply #360 capsules Refills: 3
☐ 30-day supply #120 capsules Refills: 11

Download the enrollment form, then submit it to Banner Patient Support
BAFIERTAMhcp.com/pdf/bafiertam-patient-enrollment-form.pdf

If the patient has not provided consent on the enrollment form, they can easily enroll in our services these two ways:

1 Enrolling and providing consent electronically on the BAFIERTAM consent portal
allcareconsent.com/user-information

2 If eligible,† enrolling in the Copay Program and providing consent
copay.bafiertam.com

Please see Important Safety Information on page 8 and the full Prescribing Information.

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Important Safety Information

Contraindications

BAFIERTAM is contraindicated in patients

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- Taking dimethyl fumarate or diroximel fumarate.

Warnings and Precautions

Anaphylaxis and Angioedema

- BAFIERTAM can cause anaphylaxis and angioedema after the first dose or at any time during treatment. Signs and symptoms in patients taking dimethyl fumarate (the prodrug of BAFIERTAM) have included difficulty breathing, urticaria, and swelling of the throat and tongue. Patients should be instructed to discontinue BAFIERTAM and seek immediate medical care should they experience signs and symptoms of anaphylaxis or angioedema.

Progressive Multifocal Leukoencephalopathy (PML)

- PML has occurred in patients with MS treated with dimethyl fumarate (the prodrug of BAFIERTAM). PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. A fatal case of PML occurred in a patient who received dimethyl fumarate (the prodrug of BAFIERTAM) for 4 years while enrolled in a clinical trial.
- PML has also occurred in patients taking dimethyl fumarate in the postmarketing setting in the presence of lymphopenia ($<0.9x10^9$/L). While the role of lymphopenia in these cases is uncertain, the PML cases have occurred predominantly in patients with lymphocyte counts $<0.8x10^9$/L persisting for more than 6 months.
- At the first sign or symptom suggestive of PML, withhold BAFIERTAM and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.
- Magnetic resonance imaging (MRI) findings may be apparent before clinical signs or symptoms. Monitoring with MRI for signs consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present.

Herpes Zoster and Other Serious Opportunistic Infections

- Serious cases of herpes zoster have occurred with dimethyl fumarate (the prodrug of BAFIERTAM), including disseminated herpes zoster, herpes zoster ophthalmicus, herpes zoster meningoencephalitis, and herpes zoster meningomyelitis. These events may occur at any time during treatment. Monitor patients on BAFIERTAM for signs and symptoms of herpes zoster. If herpes zoster occurs, appropriate treatment for herpes zoster should be administered.

Please see the full Prescribing Information.

- Other serious opportunistic infections have occurred with dimethyl fumarate (the prodrug of BAFIERTAM), including cases of serious viral (herpes simplex virus, West Nile virus, cytomegalovirus), fungal (Candida and Aspergillus), and bacterial (Nocardia, Listeria monocytogenes, Mycobacterium tuberculosis) infections. These infections have been reported in patients with reduced absolute lymphocyte counts (ALC) as well as in patients with normal ALC. These infections have affected the brain, meninges, spinal cord, gastrointestinal tract, lungs, skin, eye, and ear. Patients with symptoms and signs consistent with any of these infections should undergo prompt diagnostic evaluation and receive appropriate treatment.
- Consider withholding BAFIERTAM treatment in patients with herpes zoster or other serious infections until the infection has resolved.

Lymphopenia

- BAFIERTAM may decrease lymphocyte counts. In the MS placebo-controlled trials with dimethyl fumarate (the prodrug of BAFIERTAM), mean lymphocyte counts decreased by approximately 30% during the first year of treatment with dimethyl fumarate and then remained stable. Four weeks after stopping dimethyl fumarate, mean lymphocyte counts increased, but did not return to baseline. Six percent (6%) of dimethyl fumarate patients and <1% of placebo patients experienced lymphocyte counts $<0.5x10^9$/L (lower limit of normal $0.91x10^9$/L). The incidence of infections (60% vs 58%) and serious infections (2% vs 2%) was similar in patients treated with dimethyl fumarate or placebo, respectively. There was no increased incidence of serious infections observed in patients with lymphocyte counts $<0.8x10^9$/L or $<0.5x10^9$/L in controlled trials, although one patient in an extension study developed PML in the setting of prolonged lymphopenia (lymphocyte counts predominantly $<0.5x10^9$/L for 3.5 years).
- In controlled and uncontrolled clinical trials with dimethyl fumarate, 2% of patients experienced lymphocyte counts $<0.5x10^9$/L for at least 6 months, and in this group, the majority of lymphocyte counts remained $<0.5x10^9$/L with continued therapy. Neither BAFIERTAM nor dimethyl fumarate have been studied in patients with preexisting low lymphocyte counts.
- Obtain a CBC, including lymphocyte count, before initiating treatment with BAFIERTAM, 6 months after starting treatment, and then every 6 to 12 months thereafter, and as clinically indicated. Consider interruption of BAFIERTAM in patients with lymphocyte counts less than $0.5x10^9$/L persisting for more than 6 months. Given the potential for delayed recovery of lymphocyte counts, continue to obtain lymphocyte counts until their recovery if BAFIERTAM is discontinued or interrupted because of lymphopenia. Consider withholding treatment from patients with serious infections until resolution. Decisions about whether or not to restart BAFIERTAM should be individualized based on clinical circumstances.

Liver Injury

- Clinically significant cases of liver injury have been reported in patients treated with dimethyl fumarate (the prodrug of BAFIERTAM) in the postmarketing setting. The onset has ranged from a few days to several months after initiation of treatment. Signs and symptoms of liver injury, including elevation of serum aminotransferases to 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 observed. These abnormalities resolved upon treatment discontinuation. Some cases required hospitalization. None of the reported cases resulted in liver failure, liver transplant, or death. However, the combination of new serum aminotransferase elevations with increased levels of bilirubin caused by drug-induced hepatocellular injury is an important predictor of serious liver injury that may lead to acute liver failure, liver transplant, or death in some patients.

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- Elevations of hepatic transaminases (most no greater than 3 times the upper limit of normal) were observed during controlled trials.
- Obtain serum aminotransferase, alkaline phosphatase, and total bilirubin levels before initiating BAFIERTAM and during treatment, as clinically indicated. Discontinue BAFIERTAM if clinically significant liver injury induced by BAFIERTAM is suspected.

Flushing

- BAFIERTAM may cause flushing (e.g., warmth, redness, itching, and/or burning sensation). In clinical trials of dimethyl fumarate (the prodrug of BAFIERTAM), 40% of dimethyl fumarate-treated patients experienced flushing. Studies with dimethyl fumarate show that administration of non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes prior to dosing may reduce the incidence or severity of flushing. In the BAFIERTAM studies, the presence of food did not impact the incidence of flushing.

Serious Gastrointestinal Reactions

- Serious gastrointestinal reactions, including perforation, ulceration, hemorrhage, and obstruction, some with fatal outcomes, have been reported in the postmarketing setting with the use of fumaric acid esters, including dimethyl fumarate, with or without concomitant aspirin use. The majority of these events have occurred within 6 months of fumaric acid ester treatment initiation. In controlled clinical trials, the incidence of serious gastrointestinal adverse events was 1% in patients treated with dimethyl fumarate; these events, none of which were fatal, included vomiting (0.3%) and abdominal pain (0.3%)
- Monitor patients, promptly evaluate, and discontinue BAFIERTAM for new or worsening severe gastrointestinal signs and symptoms.

Adverse Reactions

- The most common adverse reactions (incidence ≥10% and ≥2% more than placebo) for dimethyl fumarate (the prodrug of BAFIERTAM) were flushing, abdominal pain, diarrhea, and nausea.
- Gastrointestinal adverse reactions: Dimethyl fumarate caused GI events (e.g., nausea, vomiting, diarrhea, abdominal pain, and dyspepsia). In clinical trials, the incidence of GI events was higher early in the course of treatment (primarily during the first month) and usually decreased over time in patients treated with dimethyl fumarate compared with placebo. Four percent (4%) of patients treated with dimethyl fumarate and less than 1% of patients on placebo discontinued due to gastrointestinal events. The incidence of serious GI events was 1% in patients treated with dimethyl fumarate.
- Hepatic transaminases: An increased incidence of elevations of hepatic transaminases in patients treated with dimethyl fumarate in clinical trials was seen primarily during the first 6 months of treatment, and most patients with elevations had levels <3 times the upper limit of normal (ULN). Elevations of alanine aminotransferase and aspartate aminotransferase to ≥3 times the ULN occurred in a small number of patients treated with both dimethyl fumarate and in patients on placebo, and were balanced between the groups. There were no elevations in transaminases ≥3 times the ULN with concomitant elevations in total bilirubin >2 times the ULN. Discontinuations due to elevated hepatic transaminases were <1%, and were similar in patients treated with dimethyl fumarate or placebo.
- Eosinophilia adverse reactions: A transient increase in mean eosinophil counts was seen during the first 2 months of therapy with dimethyl fumarate.

Please see the full Prescribing Information.

"For my active lifestyle, BAFIERTAM works. **It gives me the confidence** that I can do the things I like to do." **– Annette, living with RMS since 1998**

See What Makes BAFIERTAM Different
BAFIERTAMhcp.com/monomethyl-fumarate

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(monomethyl fumarate) delayed-release capsules 95mg

You've been treating your patients with MMF for years.

BAFIERTAM Is the Easy Choice, Pure & Simple

- Delivering your patients the proven efficacy you've come to count on
- Well-established tolerability and safety profile
- The support needed for patients to start and continue therapy

info@bannerls.com

Banner Life Sciences® is a specialty pharmaceutical company that has been committed to advancing human health through scientific innovation since 1992. We identify patients' unmet clinical needs, then leverage a proven history of formulation expertise and proprietary technologies to develop medicines that help people to live better lives.

BANNER® LIFE SCIENCES