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

TAKE THE NEXT STEP WITH

A New-Generation Fumarate for the Treatment of Relapsing Forms of Multiple Sclerosis

Indication and Select Important Safety Information

What is BAFIERTAM® (monomethyl fumarate)?

- BAFIERTAM is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- It is not known if BAFIERTAM is safe and effective in children.

Who should not take BAFIERTAM?

- Do not take BAFIERTAM if you: have had an allergic reaction (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing) to monomethyl fumarate, dimethyl fumarate, diroximel fumarate, or any of the ingredients in BAFIERTAM.
- Do not take BAFIERTAM if you are taking dimethyl fumarate or diroximel fumarate.

Please see additional Important Safety Information on pages 7 and 8 and the accompanying full Prescribing Information and Patient Information.

Whether you're switching to BAFIERTAM® (monomethyl fumarate) from another treatment or BAFIERTAM is your first treatment for relapsing multiple sclerosis (MS), you may have questions. This brochure is intended to give you information about a new-generation fumarate that directly delivers its active agent without requiring conversion in the gastrointestinal (GI) tract.

Why BAFIERTAM?

Direct delivery of the active agent avoids GI conversion

Established efficacy and well-understood safety profile

Comprehensive patient support services

Financial assistance for eligible patients

Learn more at BAFIERTAM.com/Consider.

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What Is BAFIERTAM?

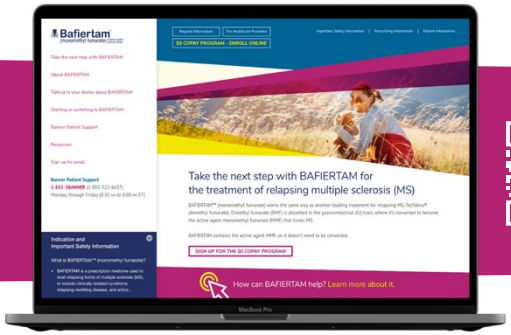
BAFIERTAM is an oral, disease-modifying therapy used to treat relapsing MS—meaning it modifies, or changes, the course of MS.

What Makes BAFIERTAM Different?

BAFIERTAM goes direct. It is the only oral fumarate for relapsing MS that is not a prodrug, meaning it contains the active agent monomethyl fumarate (MMF) without requiring conversion in the gut. Other oral fumarates need to be converted in the GI tract to the active agent MMF.

No dietary restrictions

- BAFIERTAM can be taken with or without food
- There are no restrictions on fat/caloric content



Scan to visit
BAFIERTAM.com/Consider

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How Will BAFIERTAM Help My MS?

The efficacy of BAFIERTAM was established in 2 clinical trials for its prodrug, dimethyl fumarate (DMF). When DMF is broken down in the body, it becomes MMF, the active agent in BAFIERTAM.

A proven active agent shown to*:

1. Reduce the number of relapses
2. Delay the progression of disability
3. Slow the development of brain lesions

Talk to your doctor to see if BAFIERTAM is right for you.

Select Important Safety Information

What are the possible side effects of BAFIERTAM?

BAFIERTAM may cause serious side effects, including:

- **allergic reaction** (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing). Stop taking BAFIERTAM and get emergency medical help right away if you get any of these symptoms.
- **PML (progressive multifocal leukoencephalopathy)** a rare brain infection that usually leads to death or severe disability over a period of weeks or months.
  - Tell your doctor right away if you get any of these symptoms of PML:
    - weakness on one side of the body that gets worse
    - clumsiness in your arms or legs
    - vision problems
    - changes in thinking and memory
    - confusion
    - personality changes

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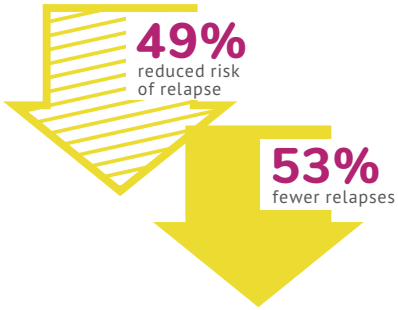
In a study of 1,234 patients with MS,† compared with placebo, DMF:

Reduced the risk of relapse by **49%** and cut the number of relapses by **53%**



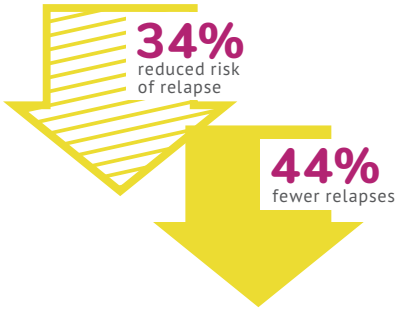
Delayed the likelihood of disease progression by **38%**

Slowed the development of brain lesions

- **90%** fewer Gd+ lesions
- **85%** fewer T2 lesions
- **73%** fewer T1 lesions

In a second study, compared with placebo,‡ DMF:

Reduced the risk of relapse by **34%** and cut the number of relapses by **44%**



Delayed the likelihood of disease progression by **21%**. It cannot be determined if this change was due to DMF.

Slowed the development of brain lesions

- **74%** fewer Gd+ lesions
- **71%** fewer T2 lesions
- **57%** fewer T1 lesions

Based on studies conducted with DMF by Biogen Inc.

*During the clinical studies, patients had neurologic exams at the very beginning (baseline), every 3 months, and whenever a relapse was suspected. A smaller group of patients (a subset) also had MRI tests at baseline, after 6 months, and at the end of the first and second years of treatment.

†In this randomized, double-blind study, patients had experienced at least 1 relapse over the year before the study or had shown at least 1 gadolinium-enhancing (Gd+) lesion within 6 weeks of the time they were randomly put into one or the other arm of the study. The median age was 39 years old, the median time since diagnosis was 4 years, and the median Expanded Disability Status Scale (EDSS) score at baseline was 2.

‡This study included an open-comparator arm. This means that some patients received a treatment considered to be effective by healthcare providers. In this randomized, double-blind study, patients had experienced at least 1 relapse over the year before the study or had shown at least 1 Gd+ lesion within 6 weeks of the time they were randomly put into one or the other arm of the study. The median age was 37 years old, the median time since diagnosis was 3 years, and the median EDSS score at baseline was 2.5.

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What Support Will I Receive With BAFIERTAM?

- **Dedicated Care Managers** provide personalized support and resources throughout the treatment process
- **Insurance Benefit Verification** helps determine patient-specific coverage requirements
- **Financial Assistance Programs** for eligible patients, including:

QuickStart Program
Banner's QuickStart Program provides a 30-day supply of BAFIERTAM to start you on treatment while your benefits are verified.

Bridge Support Program
The Bridge Support Program helps patients stay on therapy until coverage is secured.

$0 Copay Program
Eligible patients will have a $0 copay by signing up for the BAFIERTAM Savings Card.[§]

[§]The $0 Copay Program is for patients while taking BAFIERTAM and is subject to an annual cap on the amount of assistance that 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.

Indication and Important Safety Information

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- Do not take BAFIERTAM if you are taking dimethyl fumarate or diroximel fumarate.

Before taking and while you take BAFIERTAM, tell your doctor about all of your medical conditions, including if you:

- have liver problems
- have or have had low white blood cell counts or an infection
- are pregnant or plan to become pregnant. It is not known if BAFIERTAM will harm your unborn baby
- are breastfeeding or plan to breastfeed. It is not known if BAFIERTAM passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using BAFIERTAM.

Tell your doctor about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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  a rare brain infection that usually leads to death or severe disability over a period of weeks or months.
  - Tell your doctor right away if you get any of these symptoms of PML:
    - weakness on one side of the body that gets worse
    - clumsiness in your arms or legs
    - vision problems
    - changes in thinking and memory
    - confusion
    - personality changes

Important Safety Information (continued)

- **herpes zoster infections (shingles)**, including central nervous system infections
- **other serious infections**
- **decreases in your white blood cell count.** Your doctor should do a blood test to check your white blood cell count before you start treatment with BAFIERTAM and while you are on therapy. You should have blood tests after 6 months of treatment and every 6 to 12 months after that.
- **liver problems.** BAFIERTAM may cause serious liver problems that may lead to liver failure, a liver transplant, or death. Your doctor should do blood tests to check your liver function before you start taking BAFIERTAM and during treatment if needed.
  - Tell your doctor right away if you get any of these symptoms of a liver problem during treatment:
    - severe tiredness
    - loss of appetite
    - pain on the right side of your stomach
    - have dark or brown (tea color) urine
    - yellowing of your skin or the white part of your eyes

The most common side effects of BAFIERTAM include:

- flushing, redness, itching, or rash
- nausea, vomiting, diarrhea, stomach pain, or indigestion
- Flushing and stomach problems are the most common reactions, especially at the start of treatment, and may decrease over time. Call your doctor if you have any of these symptoms and they bother you or do not go away. Ask your doctor if taking aspirin before taking BAFIERTAM may reduce flushing.

These are not all the possible side effects of BAFIERTAM. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov.**

Please see the accompanying full Prescribing Information and Patient Information.

This information does not take the place of talking with your doctor about your medical condition or your treatment.