

# Facts About BAFIERTAM: a New-Generation Fumarate



## 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 at the end of this fact sheet and the accompanying full [Prescribing Information](#) and [Patient Information](#).

 **Bafiertam**<sup>™</sup>  
(monomethyl fumarate) delayed-release capsules 95mg

# Facts About BAFIERTAM

Whether you're switching to BAFIERTAM™ (monomethyl fumarate) from another treatment or BAFIERTAM is your first treatment for relapsing forms of multiple sclerosis (MS), you may have questions. This fact sheet is intended to give you the information you may be looking for as you prepare to start treatment with BAFIERTAM, a disease-modifying therapy used to treat relapsing MS in adults.

## How does BAFIERTAM work?

BAFIERTAM treats relapsing MS the same way as the leading oral treatment, Tecfidera® (dimethyl fumarate), otherwise known as DMF.

DMF is absorbed in the gastrointestinal (GI) tract, where it's converted to become the active agent monomethyl fumarate (MMF) that treats MS. BAFIERTAM contains the active agent MMF, so it doesn't need to be converted.

## What could BAFIERTAM do for me?

DMF was studied in 2 clinical trials and was shown to reduce the number of relapses, delay the progression of disability, and slow the development of brain lesions in MS.

When DMF is absorbed in the GI tract, it's converted to become the active agent MMF that treats MS.

## How does BAFIERTAM compare with other treatments?

There are different oral therapies used to treat relapsing MS. The leading prescribed oral treatment is DMF.

DMF has to be metabolized in the gut to become the active agent to treat MS. BAFIERTAM directly provides the same active agent as DMF, giving you the same benefits without needing to be converted in the gut.

## How do I get started on BAFIERTAM?

Before starting BAFIERTAM, your healthcare provider will draw your blood to check your liver function and your complete blood count. Additional blood tests are then needed during treatment. Six months after you start treatment, you will have another blood draw. From there, you should expect annual, semi-annual, or as-needed blood tests.

Even if you are already taking another fumarate, you may still need a blood test.

## How do I take BAFIERTAM?

Follow the instructions you receive from your doctor.

If BAFIERTAM is your first oral medicine for relapsing MS, you will begin treatment with half the dose—just one 95-mg capsule by mouth twice a day. After 7 days, your doctor will likely increase you to the full dose of two 95-mg capsules (190 mg) twice a day.

If you are already taking another fumarate, your doctor may start you on the full dose of BAFIERTAM.

BAFIERTAM can be taken with or without food. Swallow BAFIERTAM capsules whole and intact. Do not crush, chew, or mix the contents with food.

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## I've already been treated with another therapy. How will switching to BAFIERTAM impact the continuity of my care?

Switching to BAFIERTAM is seamless. If you are taking another fumarate, your doctor can start you on the full dose of BAFIERTAM. If you are taking another MS therapy, your doctor may begin treatment with half the dose—just one 95-mg capsule by mouth twice a day. After 7 days, your doctor will likely increase you to the full dose of two 95-mg capsules (190 mg) twice a day. Your healthcare provider may need to draw your blood to check your liver function and blood count.

## What are the most common side effects of BAFIERTAM?

Like all medicines, BAFIERTAM may cause side effects. Some of the most common side effects of BAFIERTAM are flushing, redness, itching, or rash.

### **BAFIERTAM may cause serious side effects, including:**

- ▶ Allergic reaction
- ▶ Progressive multifocal leukoencephalopathy (PML)
- ▶ Herpes zoster infections (shingles)
- ▶ Other serious infections
- ▶ Decreased white blood cell count
- ▶ Liver problems that can be serious and may lead to liver failure, the need for a liver transplant, or death

GI side effects—like nausea, vomiting, abdominal pain, and diarrhea—tend to occur more commonly during the first month of treatment.

To help lessen GI side effects, it is recommended that you take BAFIERTAM without food. You can take BAFIERTAM with food, if you wish. There is no need to avoid high-fat, high-calorie meals or snacks, as required with some other oral medicines.

## What kind of patient support does BAFIERTAM offer?

Banner Patient Support has a team of dedicated Care Managers who can help you access BAFIERTAM by verifying your benefits, assessing eligibility for patient financial assistance, as well as determining if you qualify for savings on your copays. If you have additional questions or want to learn more, please call Banner Patient Support.



**Banner Patient Support**  
**1-855-3BANNER (1-855-322-6637)**

**Monday through Friday**  
**8:30 AM to 8:00 PM ET**

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## Important Safety Information (continued)

**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.**

### **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
- **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](https://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.

