

Understanding Your Multiple Sclerosis (MS) Treatment Is Important

Having the right conversation with your MS healthcare provider is essential. Being prepared with questions like those below can lead to a clear and focused discussion.

Questi

Notes:

ions for your next visit	
	How does BAFIERTAM work?
	Can you explain how BAFIERTAM can delay the progression of physical disability?
	What impact will BAFIERTAM have on my relapses and MRI lesions?
	How is BAFIERTAM different from other fumarates?
	What side effects should I expect with BAFIERTAM?
	What can I do to limit the onset of any side effects?
	Do I need to be concerned about what or when I eat when I take BAFIERTAM?
	Will BAFIERTAM interact with other prescription drugs I take?
	Is BAFIERTAM easy to swallow?
	How soon can I get pregnant if I discontinue BAFIERTAM?
	How easy is it to get started on BAFIERTAM?
	Is there specific medical testing needed to get started?
	What patient support is available with BAFIERTAM?

Indication and 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.

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.

Please see the accompanying full <u>Prescribing Information</u> and <u>Patient Information</u>.

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

