What is BAFIERTAM?
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.

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. See “What are the ingredients in BAFIERTAM?” for a complete list of ingredients.
• 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
  ° confusion
  ° vision problems
  ° changes in thinking and memory
  ° clumsiness in your arms or legs
  ° 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
• changes in thinking and memory
• changes in vision
• loss of appetite
• diarrhea
• changes in feeling
• indigestion
• muscle cramps
• stomach pain
• weight loss
• changes in the way you smell or taste
• pain in your chest, back, or leg
• dizziness
• bone pain
• headache
• heartburn
• skin rash
• cold and flu symptoms
• sore throat
• changes in mood
• sleeping problems
• changes in sex drive or in the amount of sex that you want

How should I store BAFIERTAM?
• Store BAFIERTAM in the original container.
• Protect the capsules from light.
• Store unopened bottles of BAFIERTAM in the refrigerator between 35°F to 46°F (2°C to 8°C)
• Store opened bottles of BAFIERTAM at room temperature between 68°F to 77°F (20°C to 25°C). BAFIERTAM capsules are good for 3 months after the bottle is opened.

For more information go to dailymed.nlm.nih.gov.

General Information about the safe and effective use of BAFIERTAM
Medicines are sometimes prescribed for purposes other than those listed in this Patient Information. Do not use BAFIERTAM for a condition for which it was not prescribed. Do not give BAFIERTAM to other people, even if they have the same symptoms that you have. It may harm them.
If you would like more information, talk to your doctor or pharmacist. You can ask your pharmacist or doctor for information about BAFIERTAM that is written for health professionals.

What are the ingredients in BAFIERTAM?
Active ingredient: monomethyl fumarate
Inactive ingredients: Glyceryl caprylate/caprate; lactic acid; polyoxyl 40 hydrogenated castor oil; and povidone K30. The capsule shell, printed with black ink, contains the following inactive ingredients: gelatin; solution of sorbitans and sorbitol; and titanium dioxide. The coating system includes the following inactive ingredients: colloidal anhydrous silica, GMCC Type 1 mono and di-glycerides, hypromellose type 2910, methacrylic acid and ethyl acrylate copolymer, polyethylene glycol (MW=400), polyvinyl alcohol part hydrolyzed, sodium lauryl sulfate, talc, titanium dioxide and triethyl citrate.

Manufactured by: Banner Life Sciences LLC, High Point, NC 27265, www.BAFIERTAM.com or call 1-800-456-2255

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: May/2021