

Patient Information
BAFIERTAM® (bah"feer'tam)
(monomethyl fumarate)
delayed-release capsules, for oral use

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.
- It is not known if BAFIERTAM is safe and effective in children.

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.
 - **Pregnancy Registry:** There is a pregnancy registry for women who take BAFIERTAM during pregnancy. If you become pregnant while taking BAFIERTAM, talk to your doctor about enrolling in the pregnancy registry. You can enroll or your healthcare provider can enroll you by calling 1-866-663-95MG (1-866-663-9564). The purpose of this registry is to collect information about the health of you and your 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

How should I take Bafiertam?

- Take BAFIERTAM exactly as your doctor tells you to take it.
- You will be given 1 strength of BAFIERTAM when starting your treatment.
- The recommended starting dose is one 95 mg capsule taken by mouth 2 times a day for 7 days.
- The recommended dose after 7 days is two 95 mg capsules taken by mouth 2 times a day.
- BAFIERTAM can be taken with or without food.
- Swallow BAFIERTAM capsules whole and intact. Do not crush, chew, or mix the contents with food.
- If you take too much BAFIERTAM, call your doctor or go to the nearest hospital emergency room right away.

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
 - vision problems
 - confusion
 - clumsiness in your arms or legs
 - changes in thinking and memory
 - 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** 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
- **serious gastrointestinal problems**, including bleeding, ulcers, blockage, and tears (perforation) of the stomach or intestines. Tell your healthcare provider right away if you have any of these symptoms during treatment:
 - Stomach-area pain that does not go away
 - Bright red or black stools (that look like tar)
 - Severe vomiting
 - Severe diarrhea
 - Coughing up blood or blood clots
 - Vomiting blood or your vomit looks like "coffee grounds"

The most common side effects of BAFIERTAM include:

- flushing, redness, itching, or rash
- nausea, vomiting, diarrhea, stomach pain, or indigestion. These events can be serious in some patients (see "BAFIERTAM may cause serious side effects including," above).
- 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.

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. Throw away BAFIERTAM capsules if the bottle has been opened for more than 3 months.
- Capsules may become deformed if kept at high temperatures.
- **Keep BAFIERTAM and all medicines out of the reach of children.**

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 bicarbonate, sodium lauryl sulfate, talc, titanium dioxide and triethyl citrate.

Manufactured by: Banner Life Sciences LLC High Point, NC 27265
www.BAFIERTAM.com or call 1-866- MMF-95MG

This Patient Information has been approved by the U.S. Food and Drug Administration.

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