



## Bafiertam™ (monomethyl fumarate) – New drug approval

- On April 28, 2020, the [FDA approved](#) Banner Life Sciences' [Bafiertam \(monomethyl fumarate\)](#), for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- Bafiertam is bioequivalent to a prodrug of [Tecfidera® \(dimethyl fumarate\)](#), another drug used for relapsing forms of MS.
- The efficacy of Bafiertam is based upon bioavailability studies in healthy subjects comparing oral Tecfidera to Bafiertam.
- Bafiertam is contraindicated in patients with:
  - With known hypersensitivity to monomethyl fumarate, dimethyl fumarate, diroximel fumarate ([Vumerity™](#)), or to any of the excipients of Bafiertam. Reactions may include anaphylaxis or angioedema.
  - Taking dimethyl fumarate or diroximel fumarate.
- Warnings and precautions for Bafiertam include anaphylaxis and angioedema; progressive multifocal leukoencephalopathy; herpes zoster and other serious opportunistic infections; lymphopenia; liver injury; and flushing.
- The most common adverse reactions (incidence for dimethyl fumarate [the prodrug of Bafiertam]  $\geq 10\%$  and  $\geq 2\%$  more than placebo) were flushing, abdominal pain, diarrhea, and nausea.
- The recommended starting dosage for Bafiertam is 95 mg twice a day orally for 7 days. After 7 days, the dosage should be increased to the maintenance dosage of 190 mg (administered as two 95 mg capsules) twice a day orally.
  - Blood tests are required prior to initiation of Bafiertam.
  - Administration of non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes prior to Bafiertam dosing may reduce the incidence or severity of flushing.
- Banner Life Sciences' launch plans for Bafiertam are pending. Bafiertam will be available as a 95 mg delayed-release capsule.



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