

| <b>Patient Information</b><br><b>Dimethyl Fumarate Delayed-Release Capsules</b><br><b>(dye meth' il fue' ma rate)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
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| <p><b>What are dimethyl fumarate delayed-release capsules?</b></p> <ul style="list-style-type: none"> <li>• Dimethyl fumarate delayed-release capsules are prescription medicines used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.</li> <li>• It is not known if dimethyl fumarate delayed-release capsules is safe and effective in children under 18 years of age</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <p><b>Who should not take dimethyl fumarate delayed-release capsules?</b></p> <ul style="list-style-type: none"> <li>• Do not use dimethyl fumarate delayed-release capsules if you have had an allergic reaction (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing) to dimethyl fumarate delayed-release capsules or any of its ingredients. See below for a complete list of ingredients.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>Before taking and while you take dimethyl fumarate delayed-release capsules, tell your doctor if you have or have had:</b></p> <ul style="list-style-type: none"> <li>• low white blood cell counts or an infection</li> <li>• any other medical conditions</li> </ul> <p><b>Tell your doctor if you are:</b></p> <ul style="list-style-type: none"> <li>• pregnant or plan to become pregnant. It is not known if dimethyl fumarate delayed-release capsules will harm your unborn baby.</li> <li>• breastfeeding or plan to breastfeed. It is not known if dimethyl fumarate passes into your breast milk. You and your doctor should decide if you will take dimethyl fumarate delayed-release capsules or breastfeed.</li> <li>• taking prescription or over-the-counter medicines, vitamins, or herbal supplements</li> </ul>                                                                                                                       |
| <p><b>How should I take dimethyl fumarate delayed-release capsules?</b></p> <ul style="list-style-type: none"> <li>• Take dimethyl fumarate delayed-release capsules exactly as your doctor tells you to take it</li> <li>• The recommended starting dose is one 120 mg capsule taken by mouth 2 times a day for 7 days</li> <li>• The recommended dose after 7 days is one 240 mg capsule taken by mouth 2 times a day</li> <li>• Dimethyl fumarate delayed-release capsules can be taken with or without food</li> <li>• Swallow dimethyl fumarate delayed-release capsules whole. Do not crush, chew, or sprinkle capsule contents on food.</li> <li>• Protect dimethyl fumarate delayed-release capsules from light. You can do this by storing the capsules in their original container.</li> <li>• If you take too much dimethyl fumarate delayed-release capsules, call your doctor or go to the nearest hospital emergency room right away.</li> </ul> |
| <p><b>What are the possible side effects of dimethyl fumarate delayed-release capsules?</b><br/> <b>Dimethyl fumarate delayed-release capsules may cause serious side effects including:</b></p> <ul style="list-style-type: none"> <li>• <b>allergic reaction</b> (such as welts, hives, swelling of the face, lips, mouth or tongue, or</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

difficulty breathing)

- **PML** a rare brain infection that usually leads to death or severe disability
- **decreases in your white blood cell count** Your doctor should do a blood test before you start treatment with dimethyl fumarate delayed-release capsules and while on therapy.
- **liver problems.** Your doctor should do blood tests to check your liver function before you start taking dimethyl fumarate delayed-release capsules 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
- **herpes zoster infections (shingles)**, including central nervous system infections
- **other serious infections**

**The most common side effects of dimethyl fumarate delayed-release capsules 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 therapy, and may decrease over time. Taking dimethyl fumarate delayed-release capsules with food may help reduce flushing. 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 dimethyl fumarate delayed-release capsules may reduce flushing.

These are not all the possible side effects of dimethyl fumarate delayed-release capsules. 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](http://dailymed.nlm.nih.gov).**

**General Information about the safe and effective use of dimethyl fumarate delayed-release capsules**

- Medicines are sometimes prescribed for purposes other than those listed in this Patient Information. Do not use dimethyl fumarate delayed-release capsules for a condition for which it was not prescribed. Do not give dimethyl fumarate delayed-release capsules 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 doctor or pharmacist for information about dimethyl fumarate delayed-release capsules that is written for healthcare professionals.
- Bottles of 14's, 46's, 60's and 180's count comes with child-resistant closure.

For more information, go to [www.accordhealthcare.us](http://www.accordhealthcare.us) or call Accord Healthcare Inc. at 1-866-941-7875.

**What are the ingredients in dimethyl fumarate delayed-release capsules?**

**Active ingredient:** dimethyl fumarate

**Inactive ingredients:** silicified microcrystalline cellulose, croscarmellose sodium, talc, colloidal anhydrous silica, magnesium stearate, triethyl citrate, methacrylic acid copolymer, methacrylic acid - methyl methacrylate copolymer (1:1). **Capsule Shell:** gelatin, titanium dioxide, FD&C blue 1, iron oxide black, iron oxide yellow, shellac, propylene glycol.

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

**Manufactured For:**

Accord Healthcare, Inc.,  
1009 Slater Road,  
Suite 210-B,  
Durham, NC 27703,  
USA

**Manufactured By:**

Intas Pharmaceuticals Limited,  
Plot No. : 457, 458,  
Village - Matoda,  
Bavla Road, Ta.- Sanand,  
Dist.- Ahmedabad - 382 210,  
INDIA.

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