

Dispense with Patient Information available at:

[www.solcohealthcare.com/druglabeling/dimethyl-fumarate-dr-capsules.pdf](http://www.solcohealthcare.com/druglabeling/dimethyl-fumarate-dr-capsules.pdf)

<p><b>Patient Information</b></p> <p><b>Dimethyl Fumarate Delayed-Release Capsules</b></p> <p>(dye-METH-il FUE-ma-rate)</p>
<p><b>What are dimethyl fumarate delayed-release capsules?</b></p> <ul style="list-style-type: none"><li>• Dimethyl fumarate delayed-release capsules are 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.</li><li>• It is not known if dimethyl fumarate delayed-release capsules are 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</li></ul>

supplements

**How should I take dimethyl fumarate delayed-release capsules?**

- Take dimethyl fumarate delayed-release capsules exactly as your doctor tells you to take it
- The recommended starting dose is one 120 mg capsule taken by mouth 2 times a day for 7 days
- The recommended dose after 7 days is one 240 mg capsule taken by mouth 2 times a day
- Dimethyl fumarate delayed-release capsules can be taken with or without food
- Swallow dimethyl fumarate delayed-release capsules whole. Do not crush, chew, or sprinkle capsule contents on food.
- Protect dimethyl fumarate delayed-release capsules from light. You can do this by storing the capsules in their original container.
- If you take too many dimethyl fumarate delayed-release capsules, call your doctor or go to the nearest hospital emergency room right away.

**What are the possible side effects of dimethyl fumarate delayed-release capsules?**

**Dimethyl fumarate delayed-release capsules may cause serious side effects including:**

- **allergic reaction** (such as welts, hives, swelling of the face, lips, mouth or tongue, or 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**
- **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 dimethyl fumarate delayed-release capsules include:**

- flushing, redness, itching, or rash
- nausea, vomiting, diarrhea, stomach pain, or indigestion. These events can be serious in some patients (see “dimethyl fumarate delayed-release capsules may cause serious side effects including,” above).
- 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.

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

**Active ingredient:** dimethyl fumarate

**Inactive ingredients:** silicified microcrystalline cellulose, croscarmellose sodium, talc, colloidal silicon dioxide, magnesium stearate, triethyl citrate, methacrylic acid and methyl methacrylate copolymer (methacrylic acid and methyl methacrylate copolymer, and sodium lauryl sulfate), methacrylic acid and ethyl acrylate copolymer dispersion (methacrylic acid and ethyl acrylate copolymer, sodium lauryl sulfate, and polysorbate 80). **Capsule Shell:** gelatin, titanium dioxide, and red iron oxide. **Black edible ink BLACK SW9008:** shellac, potassium hydroxide, and black iron oxide.

**Manufactured by:** Zhejiang Huahai Pharmaceutical Co., Ltd.

Xunqiao, Linhai, Zhejiang 317024, China

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

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