

Patient Information
VUMERITY (vue mer' i tee)
(diroximel fumarate) delayed-release capsules

What is VUMERITY?

- VUMERITY is a prescription medicine used to treat people with 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 VUMERITY is safe and effective in children.

Do not take VUMERITY if you:

- have had an allergic reaction (such as welts, hives, swelling of the face, lips, mouth or tongue, or difficulty breathing) to diroximel fumarate, dimethyl fumarate, or any of the ingredients in VUMERITY. See “**What are the ingredients in VUMERITY?**” below for a complete list of ingredients.
- are taking dimethyl fumarate.

Before taking and while you take VUMERITY, tell your doctor about all of your medical conditions, including if you:

- have liver problems.
- have kidney 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 VUMERITY will harm your unborn baby.
 - If you become pregnant while taking VUMERITY, talk to your healthcare provider about enrolling in the VUMERITY Pregnancy Registry. You can enroll in this registry by calling 1-833-569-2635 or visiting www.vumeritypregnancyregistry.com. The purpose of this registry is to monitor the health of you and your baby.
- are breastfeeding or plan to breastfeed. It is not known if VUMERITY passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using VUMERITY.

Tell your doctor about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take VUMERITY?

- Take VUMERITY exactly as your doctor tells you to take it.
- The recommended starting dose on days 1 to 7 is one capsule by mouth 2 times a day. After 7 days, the recommended dose is 2 capsules by mouth 2 times a day.
- If taken with food, avoid taking VUMERITY with a high-fat, high-calorie meal or snack.
 - Your meal or snack should contain no more than 700 calories and no more than 30 g of fat.
- Swallow VUMERITY whole. Do not crush, chew, or sprinkle capsule contents on food.
- If you take too much VUMERITY, call your doctor or go to the nearest hospital emergency room right away.

What should I avoid while taking VUMERITY?

- Do not drink alcohol at the time you take a VUMERITY dose.

What are the possible side effects of VUMERITY?

VUMERITY 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 VUMERITY 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
 - clumsiness in your arms or legs
 - vision problems
 - changes in thinking and memory
 - confusion
 - 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 VUMERITY 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 VUMERITY 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 VUMERITY include:

- flushing, redness, itching, or rash
- nausea, vomiting, diarrhea, stomach pain, or indigestion. These events can be serious in some patients (see “VUMERITY 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 VUMERITY with food (avoid high-fat, high-calorie meal or snack) 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 VUMERITY may reduce flushing.

These are not all the possible side effects of VUMERITY. 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 VUMERITY?

- Store VUMERITY at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep VUMERITY and all medicines out of the reach of children.**

General Information about the safe and effective use of VUMERITY

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information. Do not use VUMERITY for a condition for which it was not prescribed. Do not give VUMERITY 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 VUMERITY that is written for healthcare professionals.

What are the ingredients in VUMERITY?

Active ingredient: diroximel fumarate

Inactive ingredients: crospovidone, colloidal silicon dioxide, magnesium stearate (non-bovine), methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, talc, and triethyl citrate. **Capsule Shell:** carrageenan, hypromellose, potassium chloride, and titanium dioxide. **Capsule Shell Ink:** iron oxide, potassium hydroxide, propylene glycol, and shellac.

Manufactured for: Biogen Inc., Cambridge, MA 02142, www.VUMERITY.com or call 1-800-456-2255

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