

I WON'T LET RELAPSING MS TAKE AWAY

Getting started on VUMERITY

What is VUMERITY® (diroximel fumarate)?

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.

Important Safety Information

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—or if you are taking dimethyl fumarate.

Please see <u>Important Safety Information</u> on pages 4-5 and 15-16 and full <u>Prescribing</u> <u>Information</u>, including <u>Patient Information</u>.



WHAT'S INSIDE

ABOUT VUMERITY

- 4 Important Safety Information
- 6 Before taking and how to take VUMERITY
- 7 VUMERITY and food
- 8 What else to know when taking VUMERITY
- 9 Most common side effects
- 10 Additional considerations and staying on track

RESOURCES & SUPPORT

- 11 Biogen Support Services
- 12 <u>Biogen Support Coordinators,</u> <u>Nurse Educators, and Financial</u> <u>& Insurance Assistance</u>
- 13 Events

TREATING RELAPSING MS

- 15 Important Safety Information
- 17 VUMERITY effectiveness

FIND OUT HOW TO PAY AS LITTLE AS \$0 FOR VUMERITY.

Eligibility and limitations apply. See more details on the <u>VUMERITY website</u>.



ABOUT VUMERITY

IN THIS SECTION, YOU'LL LEARN ABOUT:

- Important Safety Information
- What to do before taking and while you take VUMERITY
- How to take VUMERITY
- VUMERITY and food
- What else to know when taking VUMERITY
- Most common side effects
- Additional considerations with treatment
- Staying on track

Important Safety Information

Do not take VUMERITY® (diroximel fumarate) 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
- are taking dimethyl fumarate

Before taking and while you take VUMERITY, tell your healthcare provider 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 BlossoMS Pregnancy Registry. You can enroll in this registry by calling <u>1-833-569-2635</u> or visiting <u>www.blossomspregnancyregistry.com</u>. 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 healthcare provider about all the medicines you take including prescription and over-thecounter medicines, vitamins, and herbal supplements.

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 healthcare provider 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 healthcare provider 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

Please see full Prescribing Information, including Patient Information.

Important Safety Information (continued)

VUMERITY may cause serious side effects including (continued):

- **liver problems.** Your healthcare provider should do blood tests to check your liver function before you start taking VUMERITY and during treatment if needed. Tell your healthcare provider right away if you get any of these symptoms of a liver problem during treatment
 - o 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
 - o 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
- 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 healthcare provider if you have any of these symptoms and they bother you or do not go away. Ask your healthcare provider if taking aspirin before taking VUMERITY may reduce flushing

These are not all the possible side effects of VUMERITY. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at <u>1-800-FDA-1088</u>. For more information go to <u>dailymed.nlm.nih.gov</u>

Please see full **Prescribing Information**, including **Patient Information**.



BEFORE TAKING VUMERITY

Before taking and while you take VUMERITY, **tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

It's also important to share 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 BlossoMS Pregnancy Registry. You can enroll in this registry by calling <u>1-833-569-2635</u> or visiting <u>www.blossomspregnancyregistry.com</u>. 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

Your healthcare provider should do a blood test to **check your white blood cell count and liver function** before you start treatment with VUMERITY and while you're on therapy.

HOW TO TAKE VUMERITY

VUMERITY is taken as two pills twice a day—with or without food. Taking VUMERITY exactly as prescribed by your healthcare provider gives you the best chance of getting its full benefits. The medication is meant to be swallowed whole, not crushed, chewed, or sprinkled on food.

If you decide to take your dose of VUMERITY with food, please see page 6 for more information and meal examples.



If you take too much VUMERITY, call your healthcare provider or go to the nearest hospital emergency room right away.



VUMERITY AND FOOD



You can take VUMERITY with or without food. If you eat at the same time you take your VUMERITY pills, you should not take your VUMERITY with a high-fat, high-calorie meal or snack.

Eating a high-fat, high-calorie meal or snack at the time you take your VUMERITY pills could reduce the amount of the active ingredient that your body absorbs. The meal or snack should contain no more than 700 calories and no more than 30 grams of fat.

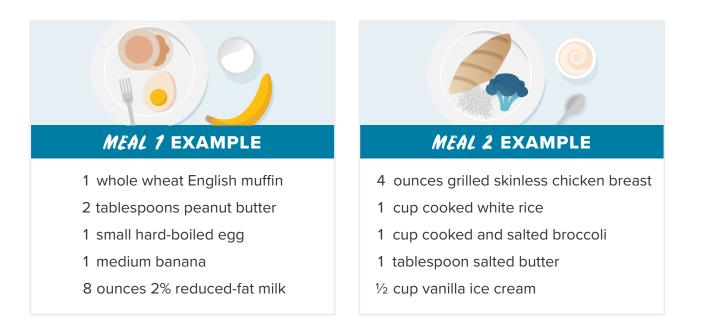


LOOKING FOR IDEAS?

If you choose to take your VUMERITY with food, and want to learn about nutritious options that are lower in fat and calories, **a nutritionist or dietitian can help**. Your healthcare team may be able to refer you to one of these specialists.

EXAMPLES OF LOW-FAT, LOW-CALORIE MEALS

To help you think of meals and snacks to take with VUMERITY, you can use these examples for inspiration.

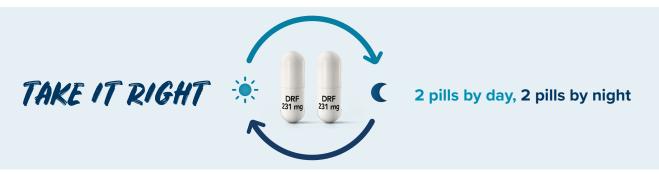




WHAT ELSE TO KNOW WHEN TAKING VUMERITY

FINDING YOUR TREATMENT ROUTINE

Taking VUMERITY exactly as prescribed by your healthcare provider gives you the best chance of getting its full benefits. You may find that **creating a daytime and nighttime routine** will help you stay on track. Try taking two pills with breakfast and two pills with dinner as an easy way to remember to take VUMERITY twice a day.



VUMERITY AND ALCOHOL



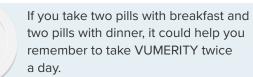
If you're taking VUMERITY, you do not have to stop drinking alcohol altogether.

But you should not drink alcohol at the same time you take your VUMERITY pills. That's because drinking alcohol at the same time you take your VUMERITY pills could reduce the amount of the active ingredient that your body absorbs.

If you have any questions about how to take VUMERITY, talk to your healthcare provider.

HELPFUL INFORMATION ON TAKING VUMERITY

Sticking to a regular schedule may help you remember to take it twice a day.

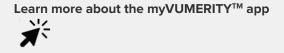




Use the myVUMERITY[™] app to be reminded of your daily doses.



Store VUMERITY at room temperature between 68°F and 77°F.



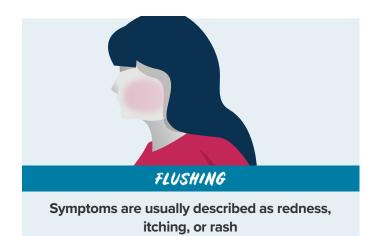
For US residents 18 years or older only. App Store is a registered trademark of Apple Inc. Google Play is a trademark of Google LLC.



MOST COMMON SIDE EFFECTS

In clinical trials, a medication called dimethyl fumarate (DMF) was tested in people with relapsing MS. Once it's processed in the body, VUMERITY takes the same active form as DMF. The information from the clinical trials is DMF data.

Flushing and stomach problems are the most common reactions, especially at the start of therapy, and **may decrease over time**.





Symptoms include nausea, vomiting, diarrhea, stomach pain, or indigestion

TIPS FOR FLUSHING



Your healthcare provider may recommend taking a non-coated aspirin (up to 325 mg) before taking VUMERITY to help with flushing.



Taking VUMERITY with food (avoid high-fat, high-calorie meal or snack) may help. See page 6 for meal ideas when taking VUMERITY with food.

TIPS FOR STOMACH PROBLEMS



Over-the-counter medicines, like antacids, may help relieve stomach problems.*

*In a small, 12-week study of people taking DMF, people recorded their experience of stomach problems, and what they did to manage them. They found that **taking over-the-counter medicines helped**.



In a separate 96 week study, about 30% of the people experienced stomach problems, but they resolved in 89% of those people. Many experienced them within the first month and on average, they lasted about a week.[†]

[†]60% of people with stomach problems experienced them within the first month of treatment, which generally lasted 7.5 days.

These are not all the possible side effects of VUMERITY. Call your healthcare provider if you have any questions about VUMERITY side effects or treatment in general.



ADDITIONAL CONSIDERATIONS

Deciding on the right treatment option for your relapsing MS is a big decision. In addition to a medicine's effectiveness, there may be some other points worth discussing with your healthcare provider. **Below are some things you may want to consider when deciding if VUMERITY is the right fit for you.**

VUMERITY AND CERTAIN MEDICATIONS



Aspirin

When taken 30 minutes before, **aspirin did not affect the effectiveness of DMF**. Your healthcare provider may recommend taking a non-coated aspirin (up to 325 mg) to help with flushing.

Oral contraceptive—norelgestromin and ethinyl estradiol

In a study using DMF, there were **no relevant effects on the combination oral contraceptive norelgestromin and ethinyl estradiol**. No additional studies have been done with oral contraceptives containing other progestogens.

Dimethyl fumarate

Do not take VUMERITY while treating with DMF.

WHAT TO KNOW ABOUT VUMERITY AND SEVERAL NON-LIVE VACCINES



A study of adults (aged 27-55) with relapsing MS investigated what happens when people receive several non-live vaccines while treating with DMF.

The study found that DMF did not weaken the body's response to three non-live vaccines:

Tetanus-diphtheria toxoid Pneumococcal Meningococcal

The safety and effectiveness of getting any other vaccine while taking DMF or VUMERITY have not been studied, and **we do not know VUMERITY's impact on vaccine effectiveness**. As with any medical decision, it's best to talk to your healthcare provider if you're considering any type of vaccination.

Have additional questions about VUMERITY? **Explore our FAQ page for more information**.

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PRESCRIBING INFORMATION	
REMINDERS	
EMAIL MY LOG	
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ACCOUNT	

STAYING ON TRACK

To help you stay on track with treatment, we created the myVUMERITY™app.

With myVUMERITY[™], you can:

- Set dosing reminders
- Log each dose
- Keep track of your lab appointments
- Email your dosing log to your healthcare team

CLICK BUTTONS BELOW TO DOWNLOAD





If you're living with relapsing multiple sclerosis (MS), know that you're not alone. **Biogen Support Services** is here to help along the way. As soon as you're prescribed VUMERITY® (diroximel fumarate), **Biogen Support Services** can provide you with financial, insurance, and treatment education and support. Remember, your healthcare team is always your best source of information.

Biogen Support Services is here for you

In this section, you'll learn about Biogen Support Services, including:



BIOGEN

Biogen Support Coordinators



Nurse Educators



Financial & Insurance Assistance



Events

GET SUPPORT TODAY

Call a Biogen Support Coordinator at <u>1-800-456-2255</u>. Monday-Friday from 8:30 AM to 8 PM ET. Hablamos español.



Biogen Support Coordinators

Once you're prescribed VUMERITY[®] (diroximel fumarate), you can get connected to a **Biogen Support Coordinator** who can help answer questions you may have. They'll provide one-on-one phone support and are ready to help you throughout treatment. They'll help you access resources you may need, including:

- Helpful information throughout your time on VUMERITY
- Connections to financial and insurance assistance to help you access your medication
- In-person or online events where you can learn from experts and people living with relapsing MS
- Follow-up calls, if you're interested, to check in and see how you are doing



Nurse Educators

Nurse Educators are registered nurses who work on behalf of Biogen, and many are MS-certified. They understand the challenges you may be facing and are ready to support you throughout your time on VUMERITY. They're available to:

- Answer questions or provide information from 8:30 AM to 8:00 PM ET, Monday through Friday, related to your relapsing MS and VUMERITY
- **Provide ongoing phone support**, including information on how to take your medication and help manage common side effects
- **Review instructions** from your healthcare provider and connect you with available resources

Although **Nurse Educators** can be a great resource for you, it's important to remember that your healthcare provider is always your best source of information.

Financial & Insurance Assistance

At Biogen, our goal is for everyone to get the support they need so they can afford their treatment. We can work with you to understand your insurance coverage and medication cost, and explore financial assistance options for your VUMERITY. **Call <u>1-800-456-2255</u> to connect.**

Understanding Your Insurance

Biogen Support Coordinators will communicate with you and your insurance company to explain coverage options and costs, including guiding you through the Prior Authorization process. They can explain complicated insurance information and changes.

Finding Financial Assistance

Biogen Support Coordinators can also help identify potential options for financial assistance with your relapsing MS medication. If you are:

- Commercially insured: if you're eligible, the Biogen Copay Program could lower your medication cost to as little as \$0.* For most commercially insured patients, VUMERITY costs \$0[†]
- **Government insured:** we can check to see if you are eligible for alternative government insurance programs
- Uninsured or underinsured: we can research other possible financial assistance available to you

*There is an annual cap on the amount of assistance that patients can receive over a one-year period. Federal and state laws and other factors may prevent or otherwise restrict eligibility. People covered by Medicare, Medicaid, the VA/DoD, or any other federal plans are not eligible to enroll. You are eligible to enroll in the **Biogen Copay Program** for as long as it is offered and you are treated with VUMERITY.

[†]65% of commercially insured patients taking VUMERITY pay \$0 compared to only 15% of those taking a generic dimethyl fumarate. (Data as of Sept 2023.) Final costs may vary based on individual plan.





Events

All VUMERITY® (diroximel fumarate) events and online webinars are free

Bring your care partner or friend along with you. It's a nice way for them to learn more about relapsing MS while expanding your support network.

Join an online webinar or event in your area

UPPORI

Biogen events and online webinars can help you learn more about VUMERITY, hear inspirational stories, and get answers to your questions. These events can connect you with others in your area who are living with relapsing MS. Be sure to talk to your healthcare provider, who is always your primary resource when it comes to your MS and your treatment.

JOIN A RELAPSING MS EVENT NEAR YOU Visit VUMERITY.com/events

Call a Biogen Support Coordinator at <u>1-800-456-2255</u>

Monday-Friday from 8:30 AM to 8 PM ET. Hablamos español.

TODA



TREATING RELAPSING MS

IN THIS SECTION, YOU'LL LEARN ABOUT:

- Important Safety Information
- VUMERITY effectiveness

What is VUMERITY[®] (diroximel fumarate)?

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- It is not known if VUMERITY is safe and effective in children

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- are taking dimethyl fumarate

Before taking and while you take VUMERITY, tell your healthcare provider 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 BlossoMS Pregnancy Registry. You can enroll in this registry by calling <u>1-833-569-2635</u> or visiting <u>www.blossomspregnancyregistry.com</u>. The purpose of this registry is to monitor the health of you and your baby
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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 healthcare provider 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

Please see full **Prescribing Information**, including **Patient Information**.

Important Safety Information (continued)

VUMERITY may cause serious side effects including (continued):

- herpes zoster infections (shingles), including central nervous system infections
- other serious infections
- decreases in your white blood cell count. Your healthcare provider 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 healthcare provider should do blood tests to check your liver function before you start taking VUMERITY and during treatment if needed. Tell your healthcare provider 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:
 - o stomach-area pain that does not go away
 - o 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
- 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 healthcare provider if you have any of these symptoms and they bother you or do not go away. Ask your healthcare provider if taking aspirin before taking VUMERITY may reduce flushing

These are not all the possible side effects of VUMERITY. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at <u>1-800-FDA-1088</u>. For more information go to <u>dailymed.nlm.nih.gov</u>

Please see full <u>Prescribing Information</u>, including <u>Patient Information</u>.



VUMERITY EFFECTIVENESS

UNDERSTANDING THE POTENTIAL BENEFITS

Once it's processed in the body, VUMERITY takes the same active form as DMF. The information from the clinical trials is DMF data.

DMF was studied in two separate 2-year clinical trials in people with relapsing-remitting MS. In the first trial, 410 people took 240 mg of DMF two times a day and 408 took placebo (a "fake" pill). In the second trial, 359 people took 240 mg of DMF two times a day and 363 took placebo.



Cuts relapses



May delay disability progression



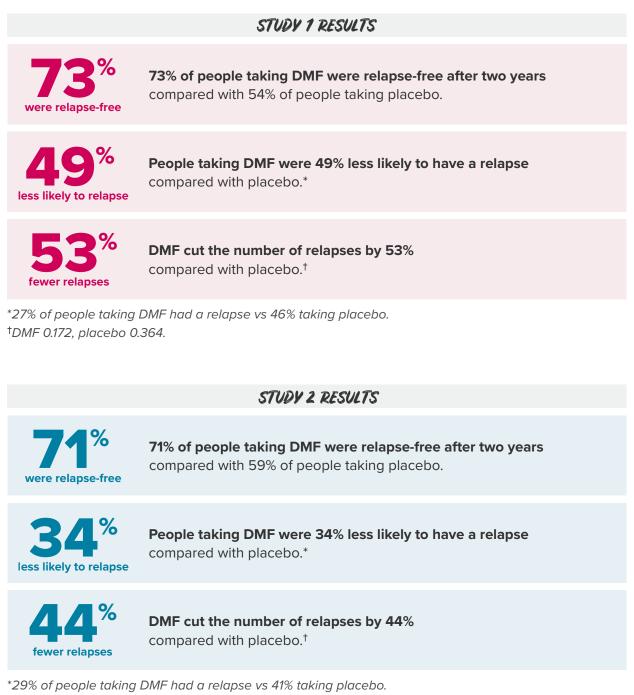
Slows development of brain lesions





CUTS RELAPSES

More than 70% of people taking DMF had no relapses after two years. Reducing the risk of relapses should be one of the goals of treatment. Although no relapsing MS medication completely gets rid of relapses, DMF has been **shown to reduce relapses compared with placebo**.



[†]DMF 0.224, placebo 0.401.



DISABILITY PROGRESSION WAS LESS LIKELY

DMF was shown to delay the progression of disability, which is an important goal of treatment.







SLOWS THE DEVELOPMENT OF BRAIN LESIONS

disappear when inflammation decreases.

To understand the impact of DMF on brain lesions, researchers looked at lesions using three different MRI techniques to determine the age and stage of the lesions. Based on all three measures, **people taking DMF had fewer lesions** compared with those taking placebo. The link between brain lesions and the progression of relapsing MS has not been confirmed.

STUDY 1 RESULTS				
ACTIVE INFLAMMATION	LONG-TERM IMPACT OF INFLAMMATION	POSSIBLE PERMANENT DAMAGE		
AVERAGE NUMBER OVER TWO YEARS				
90% fewer Gd+ lesions* for DMF	85% fewer T2 lesions [†] for DMF	fewer T1 lesions [±] for DMF		
1.8 placebo VS 0.1 DMF	17.0 placebo VS 2.6 DMF	5.6 placebo VS 1.5 DMF		
*Inflamed brain tissue that is attacked and considered "active." These lesions	[†] Scars that indicate the long-term impact of MS on the brain. They can either be new	[‡] Nerve cells in the brain that can't be repaired, which can mean a loss of function.		

STUDY 2 RESULTS

lesions or old lesions that develop again.

ACTIVE INFLAMMATION	LONG-TERM IMPACT OF INFLAMMATION	POSSIBLE PERMANENT DAMAGE	
	AVERAGE NUMBER OVER TWO YEAR	S	
fewer Gd+ lesions* for DMF	fewer T2 lesions [†] for DMF	57% fewer T1 lesions [‡] for DMF	
2.0 placebo VS 0.5 DMF	17.4 placebo VS 5.1 DMF	7.0 placebo VS 3.0 DMF	
*Inflamed brain tissue that is attacked and considered "active." These lesions disappear when inflammation decreases.	[†] Scars that indicate the long-term impact of MS on the brain. They can either be new lesions or old lesions that develop again.	[‡] Nerve cells in the brain that can't be repaired, which can mean a loss of function	

CONNECT WITH OTHERS IN THE COMMUNITY ON THE VUMERITY FACEBOOK AND INSTAGRAM PAGES





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