

VUMERITY™

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using VUMERITY?

VUMERITY contains the active ingredient diroximel fumarate. VUMERITY is used to treat multiple sclerosis.

For more information, see Section [1. Why am I using VUMERITY?](#) in the full CMI.

2. What should I know before I use VUMERITY?

Do not use if you have ever had an allergic reaction to VUMERITY or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use VUMERITY?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor if you have previously taken or are currently taking medicines containing fumaric acid or dimethyl fumarate. Tell your doctor if you are taking, or any other medicine including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with VUMERITY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use VUMERITY?

- The recommended starting dose of VUMERITY is 231 mg (one capsule) taken twice daily. After 7 days the recommended dose is 462 mg (two capsules) twice daily. Follow instructions provided, use VUMERITY until your doctor tells you to stop.
- Each capsule should be swallowed whole, with or without food. Do not crush, chew or sprinkle capsule contents on food.

More instructions can be found in Section [4. How do I use VUMERITY?](#) in the full CMI.

5. What should I know while using VUMERITY?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using VUMERITY.
- Keep all your doctor's appointments so that your progress can be checked. Your doctor will do blood and urine tests before you take VUMERITY and periodically while you are taking VUMERITY.
- Call your doctor straight away if you think you have infection, fever, flu symptoms; or if you think you have relapse symptoms - new or worsening weakness on one side of the body, clumsiness, changes in vision, thinking, or memory; confusion or personality changes lasting for more than several days.

Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly or lower dose unless your doctor has told you to.
Looking after your medicine	<ul style="list-style-type: none"> • Store in a cool, dry place below 25°C. Keep capsules in the pack until use.

For more information, see Section [5. What should I know while using VUMERITY?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: diarrhoea, stomach pain or cramps, nausea or vomiting, indigestion, any other intestinal problems, reddening of the face or body (flushing), burning sensation, hot flush, feeling hot, itchy skin, rash, pink or red blotches on skin.

Serious side effects include: infection (symptoms such as fever, severe diarrhoea), allergic reaction (swelling of face, lips, tongue; shortness of breath, wheezing, difficulty breathing), symptoms similar to an MS relapse, new or worsening weakness on one side of the body; clumsiness; changes in vision, thinking, or memory; or confusion or personality changes.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

VUMERITY™

Active ingredient(s): *diroximel fumarate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VUMERITY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VUMERITY.**

Where to find information in this leaflet:

- [1. Why am I using VUMERITY?](#)
- [2. What should I know before I use VUMERITY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use VUMERITY?](#)
- [5. What should I know while using VUMERITY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using VUMERITY?

VUMERITY contains the active ingredient diroximel fumarate.

VUMERITY is used to treat relapsing multiple sclerosis (MS).

VUMERITY slows down the progression of physical disability in people with relapsing forms of MS and decreases the number of flare ups (relapses).

Some people feel better when they start to take VUMERITY. However, VUMERITY cannot repair damage that has already been caused by MS. When you start VUMERITY you might not notice an improvement, but VUMERITY may still be working to help prevent your MS from becoming worse.

The cause of MS is not yet known, MS affects the brain and spinal cord. In MS, the body's immune system reacts against its own myelin (the 'insulation' surrounding nerve fibres). In relapsing forms of MS, people have 'exacerbations' from time to time (e.g. blurred vision, weakness in the legs or arms, or loss of control of bowel or bladder function). They are followed by periods of recovery. Recovery may be complete or incomplete. If it is incomplete there is 'progression of disability'.

Diroximel fumarate decreases the inflammation in your brain that is caused by MS and thereby reduces nerve damage.

VUMERITY works by reducing inflammatory responses in cells and helps to protect the central nervous system cells against attack. Inflammation of the brain is an important part of the MS disease process.

Safety and efficacy in children and adolescents aged less than 18 years have not been established.

2. What should I know before I use VUMERITY?

Warnings

Do not use VUMERITY if:

- you are allergic to diroximel fumarate, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any medicine containing dimethyl fumarate.
- you are suspected to suffer from a rare brain infection called progressive multifocal leukoencephalopathy (PML) or if PML has been confirmed.
- you are being treated with other medicines containing fumaric acid or dimethyl fumarate (creams, tablets or capsules).
- always check the ingredients to make sure you can use this medicine.
- the medicine has expired according to the expiry date printed on the pack or if the pack is damaged or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- have any other medical conditions: liver problems, kidney problems, infections, stomach or bowel problems.
- recently received a vaccination.
- suspect you may have shingles.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use VUMERITY if you are pregnant unless you have discussed this with your doctor. This is because VUMERITY could harm your unborn baby. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

If you are able to get pregnant, you should use reliable contraception. Check with your doctor if you intend to become pregnant. There is no information on the use of VUMERITY during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether VUMERITY passes into breast milk. Your doctor will discuss the risks and benefits of taking it if you are breast-feeding.

Blood and urine tests

- Before you start VUMERITY, your doctor will do a blood test to check the number of your white blood cells.
- Before you start VUMERITY, your doctor will do a urine test to check your kidney function.

Your doctor will make decisions about whether VUMERITY is suitable for you based on these tests.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you have previously taken or are currently taking medicines containing fumaric acid or dimethyl fumarate (creams, tablets or capsules). You should not take VUMERITY together with these medicines.

Some medicines may interfere with VUMERITY and affect how it works. These include:

- medicines which affect the kidneys, including some antibiotics (used to treat infections), “water tablets” (diuretics), certain types of painkillers (such as ibuprofen and other similar anti-inflammatory medicines and medicines purchased without a doctor’s prescription) and medicines that contain lithium.

- live vaccines.

These medicines may be affected by VUMERITY or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

4. How do I use VUMERITY?

How much to take

- The recommended starting dose of VUMERITY is 231 mg (one capsule) taken twice daily. After 7 days the recommended dose is 462 mg (two capsules) twice daily.
- Each capsule should be swallowed whole. Do not crush, chew or sprinkle capsule contents on food.
- Follow the instructions provided and use VUMERITY until your doctor tells you to stop.

When to take VUMERITY

- Twice a day, with or without food.
- Taking it at the same time each day (e.g. at morning during breakfast and at night during dinner) will help you remember when to take it.
- Your doctor may temporarily reduce your dose. Do not reduce your dose unless your doctor tells you to.

If you forget to take VUMERITY

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much VUMERITY

If you think that you have used too much VUMERITY, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26 in Australia or 0800 764 766 in New Zealand)**, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using VUMERITY?

Things you should do

Keep all of your doctor's appointments so that your progress can be checked.

If you are about to have any blood or urine tests, tell your doctor that you are taking VUMERITY.

Blood and urine test results may be affected by treatment with VUMERITY.

Your doctor will continue blood and urine tests periodically while you are taking VUMERITY as VUMERITY may affect your white blood cells, kidneys and liver. VUMERITY may cause increases in the level of liver enzymes that will show up in a blood test. VUMERITY may cause proteins (such as albumin) to be detected in a urine test.

Take VUMERITY exactly as your doctor has prescribed.

Tell your doctor if you are going to be vaccinated.

Tell your partner or caregiver about your treatment.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking VUMERITY.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Call your doctor straight away if you:

- have lower lymphocyte counts (a type of white blood cell). Having a low white blood cell count can increase your risk of infection, including PML. PML may lead to severe disability or death. PML has occurred after 1 to 5 years of treatment with the related medicine dimethyl fumarate and so your physician should continue to monitor your white blood cells throughout your treatment, and you should remain observant of any potential symptoms of PML as described below. The risk of PML may be higher if you have previously taken a medicine that suppresses your body's immune system.

The symptoms of PML may be similar to an MS relapse. Symptoms may include new or worsening weakness on one side of the body, clumsiness, changes in vision, thinking, or memory, or confusion or personality changes, or speech and communication difficulties lasting for more than several days.

- Therefore, if you believe your MS is getting worse or if you notice any new symptoms while you are on VUMERITY treatment, it is very important that you speak to your doctor as soon as possible. Also speak with your partner or caregivers and tell them about

your treatment. Symptoms might develop that you do not notice yourself.

- think you have an infection, have fever, or feel like you have the flu. VUMERITY may decrease lymphocyte (white blood cell) counts. White blood cells fight infection. You may get infections more easily while you are taking VUMERITY. Any infection that you already have may get worse. Infections could be serious and sometimes life-threatening. If you have a serious infection, your doctor may recommend that you stop taking VUMERITY until you recover.

Remind any doctor, dentist or pharmacist you visit that you are using VUMERITY.

Things you should not do

- Do not stop using this medicine or lower the dosage without checking with your doctor.
- Do not take VUMERITY to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VUMERITY affects you.

It is not known whether VUMERITY affects ability to drive and use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store your medicine below 25°C.
- Keep your capsules in the pack until it is time to take them.

Store it in a cool dry place away from moisture, heat or sunlight, for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Heat or dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

Discard your medicine if it has expired or is damaged.

Do not use this medicine after the expiry date.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it should be discarded due to expiry or damage, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Stomach and bowels:</p> <ul style="list-style-type: none">• Diarrhoea• Stomach pain or cramps• Nausea or vomiting• Indigestion• Any other intestinal problems <p>Body temperature and skin:</p> <ul style="list-style-type: none">• reddening of the face or body• burning sensation• hot flush, feeling hot• itchy skin• rash	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>If any of these persist or worsen, talk to your doctor as some of them may also be due to an infection or allergic reaction.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • pink or red blotches on the skin 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • signs of infection (e.g., unexplained fever, severe diarrhoea). <p>This is a serious side effect that may require medical attention.</p>	<p>Call your doctor straight away, if you notice any of these serious side effects.</p>
<ul style="list-style-type: none"> • swelling of your face, lips, tongue or other parts of the body • shortness of breath, wheezing, difficulty breathing, chest pain or discomfort • symptoms similar to an MS relapse which may be due to PML, new or worsening weakness on one side of the body; clumsiness; changes in vision, thinking, or memory; or confusion or personality changes. 	<p>Stop taking VUMERITY, call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What VUMERITY contains

Active ingredient (main ingredient)	Diroximel fumarate
Other ingredients (inactive ingredients)	methacrylic acid - ethyl acrylate copolymer (1:1) crospovidone microcrystalline cellulose colloidal anhydrous silica triethyl acetate purified talc magnesium stearate capsule shell: hypromellose titanium dioxide potassium chloride carrageenan capsule print (TekPrint SW-9008 Black Ink)
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

What VUMERITY looks like

VUMERITY is supplied as white capsules printed with “DRF 231 mg” in black ink on the capsule body. (AUST R 354530). The capsules are supplied in bottles of 106 or 120.

Further information

You can obtain more information from your doctor, pharmacist or the MS Society in your state. For treatment support visit b.yond.com.au or call 1800 286 639 (NZ: 0800 286 639).

The Patient Support Program complies with the Medicines Australia Code of Conduct and Medicines New Zealand Code of Practice, however it is not authorised or approved by the Therapeutic Goods Administration in Australia or by Medsafe in New Zealand.

Who distributes VUMERITY

VUMERITY is supplied in Australia by:

Biogen Australia Pty Ltd
ABN 30 095 760 115
Level 4, 2 Banfield Road
Macquarie Park NSW 2113

VUMERITY is supplied in New Zealand by:

Biogen NZ Biopharma Limited
188 Quay Street

Auckland

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