

Dimethyl Fumarate MSN

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.

1. Why am I taking Dimethyl Fumarate MSN?

Dimethyl Fumarate MSN contains the active ingredient dimethyl fumarate. Dimethyl Fumarate MSN is used to treat relapsing multiple sclerosis (MS).

For more information, see Section [1. Why am I taking Dimethyl Fumarate MSN?](#) in the full CMI.

2. What should I know before I take Dimethyl Fumarate MSN?

Do not use if you have ever had an allergic reaction to dimethyl fumarate 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 take Dimethyl Fumarate MSN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dimethyl Fumarate MSN 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 take Dimethyl Fumarate MSN?

- The recommended starting dose of Dimethyl Fumarate MSN is 120 mg taken twice daily. After 7 days the recommended dose is 240 mg twice daily.

More instructions can be found in Section [4. How do I take Dimethyl Fumarate MSN?](#) in the full CMI.

5. What should I know while taking Dimethyl Fumarate MSN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Dimethyl Fumarate MSN.• If you are about to have any blood or urine tests, tell your doctor that you are taking Dimethyl Fumarate MSN. Blood and urine test results may be affected by treatment with Dimethyl Fumarate MSN.• Tell your doctor if you are going to be vaccinated.• Call your doctor right away if you think you have an infection, have fever, or feel like you have the flu.• Call your doctor right away if you think you are experiencing 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 lasting for more than several days.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine or lower the dosage without checking with your doctor..• Do not take Dimethyl Fumarate MSN to treat any other complaints unless your doctor tells you to
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Dimethyl Fumarate MSN affects you.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol for 1 hour after taking this medicine, as alcohol may lead to gastrointestinal side effects.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place away from moisture, heat or sunlight; where the temperature stays below 25 °C

For more information, see Section [5. What should I know while taking Dimethyl Fumarate MSN?](#) in the full CMI.

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

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.

Dimethyl Fumarate MSN

Active ingredient: *dimethyl fumarate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dimethyl Fumarate MSN. **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 Dimethyl Fumarate MSN.**

Where to find information in this leaflet:

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

1. Why am I taking Dimethyl Fumarate MSN?

Dimethyl Fumarate MSN contains the active ingredient **dimethyl fumarate**.

Dimethyl Fumarate MSN is used to treat relapsing multiple sclerosis (MS).

Dimethyl Fumarate MSN 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 Dimethyl Fumarate MSN. However Dimethyl Fumarate MSN cannot repair damage that has already been caused by MS.

When you start Dimethyl Fumarate MSN you might not notice an improvement, but Dimethyl Fumarate MSN 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'.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Dimethyl fumarate has not been studied in patients with chronic progressive MS.

2. What should I know before I take Dimethyl Fumarate MSN?

Warnings

Do not use Dimethyl Fumarate MSN if:

- you are allergic to dimethyl fumarate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin.
- You are being treated with other medicines containing fumaric acid (creams or tablets/capsules).

Check with your doctor if you:

- have any other medical conditions such as
 - liver problems
 - kidney problems
 - infection
- recently received a vaccination
- 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?](#)

Shingles

Tell your doctor at the earliest opportunity if you suspect you may have shingles (a painful viral infection with a painful rash that develops on one side of the face or body).

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. There is no information on the use of Dimethyl Fumarate MSN during pregnancy. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether Dimethyl Fumarate MSN passes into breast milk. Your doctor will discuss the

risks and benefits of taking it if you are breastfeeding or planning to breastfeed.

Children

Safety and effectiveness in children younger than 18 years have not been established.

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.

Some medicines may interfere with Dimethyl Fumarate MSN and affect how it works. These include:

- medicines that contain fumaric acid (creams or tablets/capsules)
- medicines which affect immune function including other medicines to treat MS such as fingolimod, natalizumab or mitoxantrone or some other commonly used cancer medicines
- 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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dimethyl Fumarate MSN.

4. How do I take Dimethyl Fumarate MSN?

How much to take

- The recommended starting dose of Dimethyl Fumarate MSN is 120 mg taken twice daily. After 7 days the recommended dose is 240 mg twice daily.
- Your doctor may tell you to take Dimethyl Fumarate MSN with aspirin or may temporarily reduce your dose.
- Do not reduce your dose unless your doctor tells you to.

When to take Dimethyl Fumarate MSN

- Take one capsule twice a day. 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.
- Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it. The positive effects of Dimethyl Fumarate MSN may not be seen immediately. It is important to keep taking your medicine even if you feel well.
- It is important not to interrupt treatment with Dimethyl Fumarate MSN unless your doctor tells you to.

How to take Dimethyl Fumarate MSN

- Swallow each capsule whole with a glass of water. Do not crush, divide or dissolve the capsule or its contents.
- Dimethyl Fumarate MSN can be taken with or without food. For those patients who experience gastrointestinal side effects or flushing, taking Dimethyl Fumarate MSN with food may help reduce these effects.
- **Do not drink alcohol for 1 hour after taking this medicine, as alcohol may lead to gastrointestinal side effects.**

If you forget to take Dimethyl Fumarate MSN

Dimethyl Fumarate MSN should be used regularly at the same time each day.

If you miss a dose, and 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.

If you take too much Dimethyl Fumarate MSN

If you think that you have used too much Dimethyl Fumarate MSN, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, 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 taking Dimethyl Fumarate MSN?

Things you should do

Take Dimethyl Fumarate MSN exactly as your doctor has prescribed.

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 Dimethyl Fumarate MSN. Blood and urine test results may be affected by treatment with Dimethyl Fumarate MSN.

Tell your doctor if you are going to be vaccinated.

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

Remind any doctor, dentist or pharmacist you visit that you are using Dimethyl Fumarate MSN.

Tell your partner or caregiver about your treatment.

Call your doctor straight away if you:

- **think you have an infection, have fever, or feel like you have the flu.**
Dimethyl Fumarate MSN may decrease lymphocyte (white blood cell) counts. White blood cells fight infection. You may get infections more easily while you are taking Dimethyl Fumarate MSN. 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 Dimethyl Fumarate MSN until you recover
- **think you are experiencing 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 lasting for more than several days.**
These could be signs of a rare and very serious brain infection called progressive multifocal leukoencephalopathy (PML). The symptoms of PML may be similar to an MS relapse.
Having low lymphocyte levels, particularly for a long period of time can increase your risk of PML.

Things you should not do

- Do not take Dimethyl Fumarate MSN 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.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Blood and urine tests

- Before you start Dimethyl Fumarate MSN, your doctor will do a blood test to check the number of your white blood cells. Your doctor may also test these periodically during treatment.
- Before you start Dimethyl Fumarate MSN, your doctor will make sure you have results from a recent urine test to check your kidney function and may repeat the test periodically during treatment. Dimethyl Fumarate MSN may cause proteins (such as albumin) to be detected in a urine test.
- Dimethyl Fumarate MSN may also cause increases in the level of liver enzymes that will show up in a blood test.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Dimethyl Fumarate MSN affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol for 1 hour after taking this medicine, as alcohol may lead to gastrointestinal side effects.

Looking after your medicine

- Keep your capsules in the pack until it is time to take them. If you take the capsules out of the pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; where the temperature stays below 25 °C. For example, do not store it:

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

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine, it shows signs of tampering or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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
<ul style="list-style-type: none">• reddening of the face or body feeling warm, hot, burning or itchy (flushing)• loose stools (diarrhoea)• feeling sick (nausea)• stomach pain or stomach cramps• inflammation of the lining of the intestines (gastroenteritis)• being sick (vomiting)• indigestion (dyspepsia)• inflammation of the lining of the stomach (gastritis)• gastrointestinal disorder• burning sensation• hot flush, feeling hot• itchy skin (pruritus)• rash• pink or red blotches on the skin (erythema)• runny nose (rhinorrhoea).• hair thinning.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">signs of infection (e.g., unexplained fever, severe diarrhoea).	Call your doctor straight away if you notice any of these serious side effects.

Very serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">swelling of your face, lips, tongue or other parts of the bodyshortness of breath, wheezing, difficulty breathing, chest pain or discomfortsymptoms 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.	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.

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 Dimethyl Fumarate MSN contains

Active ingredient (main ingredient)	Dimethyl fumarate
Other ingredients (inactive ingredients)	microcrystalline cellulose (E460) croscarmellose sodium (E468) purified talc (E553b) colloidal anhydrous silica (E551) magnesium stearate (E572) triethyl citrate (E1505)

	methacrylic acid copolymer methacrylic acid-ethyl acrylate copolymer gelatin titanium dioxide (E171) TekPrint SW9008 black ink
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Do not take this medicine if you are allergic to any of these ingredients.

What Dimethyl Fumarate MSN looks like

Dimethyl Fumarate MSN capsules are available in two strengths: 120 mg and 240 mg.

Dimethyl Fumarate MSN 120 mg capsules are supplied as white to off white coloured enteric coated mini tablets filled in size "0" hard gelatin capsule shell with white Opaque cap and white Opaque body imprinted with "120 mg" with black ink.

Available in blister packaging containing 14 or 112 capsules (ARTG 324441) or in a container containing 14 capsules (ARTG 324442).

Dimethyl Fumarate MSN 240 mg capsules are supplied as white to off white coloured enteric coated mini tablets filled in size "0" hard gelatin capsule shell with white Opaque cap and white Opaque body imprinted with "240 mg" with black ink.

Available in blister packaging containing 14 or 56 capsules (ARTG 324440) or in a container containing 60 capsules (ARTG 324443).

Not all pack sizes may be available.

Further information

You can obtain more information from your doctor, pharmacist or the MS Society in your State, or by telephoning the MS Alliance on 1800 852 289 in Australia or 0800 852 289.

Who distributes Dimethyl Fumarate MSN

Cipla Australia Pty. Ltd
Level 1, 132 Albert Road, South Melbourne, VIC 3205
Australia This leaflet was prepared in April 2023