

PHARMACOR DIMETHYL FUMARATE

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 using PHARMACOR DIMETHYL FUMARATE?

Pharmacor Dimethyl Fumarate contains the active ingredient dimethyl fumarate. Pharmacor Dimethyl Fumarate is used to treat relapsing multiple sclerosis (MS). For more information, see Section [1. Why am I using PHARMACOR DIMETHYL FUMARATE?](#) in the full CMI.

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

2. What should I know before I use PHARMACOR DIMETHYL FUMARATE?

CMI.

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

For more information, see Section [2. What should I know before I use PHARMACOR DIMETHYL FUMARATE?](#) 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 (creams or tablets/ capsules).

You should not take Pharmacor Dimethyl Fumarate together with these medicines. Some medicines and Pharmacor Dimethyl Fumarate may interfere with each other 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 PHARMACOR DIMETHYL FUMARATE?

Follow all directions given to you by your doctor or pharmacist carefully.

The recommended starting dose of Pharmacor Dimethyl Fumarate 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 use PHARMACOR DIMETHYL FUMARATE?](#) in the full CMI.

5. What should I know while using PHARMACOR DIMETHYL FUMARATE?

Things you should do	<ul style="list-style-type: none">• Take Pharmacor Dimethyl Fumarate 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 Pharmacor Dimethyl Fumarate.• 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.
Things you should not do	<ul style="list-style-type: none">• Do not take Pharmacor Dimethyl Fumarate to treat any other complaints unless your doctor tells you to.• Do not give your medicine to anyone else, even if they are also trying to stop smoking.
Looking after your medicine	<ul style="list-style-type: none">• Store in original packaging in order to protect from light. Store below 25°C.• Keep your capsules in the pack until it is time to take them.

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

6. Are there any side effects?

Common side effects of Pharmacor Dimethyl Fumarate include: 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 Other serious side effects have also been reported: signs of infection (e.g., unexplained fever, severe diarrhoea). 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.

PHARMACOR DIMETHYL FUMARATE

Active ingredient(s): *dimethyl fumarate*

Consumer Medicine Information (CMI)

This leaflet answers some common questions about Pharmacor Dimethyl Fumarate. **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 Pharmacor Dimethyl Fumarate.**

Where to find information in this leaflet:

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

1. Why am I using PHARMACOR DIMETHYL FUMARATE?

Pharmacor Dimethyl Fumarate contains the active ingredient dimethyl fumarate.

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

Pharmacor Dimethyl Fumarate 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 Pharmacor Dimethyl Fumarate. However Pharmacor Dimethyl Fumarate cannot repair damage that has already been caused by MS. When you start Pharmacor Dimethyl Fumarate you might not notice an improvement, but Pharmacor Dimethyl Fumarate 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'.

How Pharmacor Dimethyl Fumarate works

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

Your doctor may have prescribed it for another reason.

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

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

This medicine is not addictive.

It is available only with a doctor's prescription.

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.

2. What should I know before I use PHARMACOR DIMETHYL FUMARATE?

Warnings

Do not use PHARMACOR DIMETHYL FUMARATE if:

- you are allergic to dimethyl fumarate, or any of the ingredients listed at the end of this leaflet.

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.

Always check the ingredients to make sure you can use this medicine.

Do not take Pharmacor Dimethyl Fumarate if you are being treated with other medicines containing fumaric acid (creams or tablets/capsules).

- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Talk to your doctor if you are not sure whether you should take this medicine.

Check with your doctor if you:

- liver problems
- kidney problems
- infection
- recently received a vaccination

Tell your doctor at your earliest opportunity if you suspect you have any symptoms of shingles.

Tell your doctor if you are pregnant or intend to become pregnant.

If you have not told your doctor about any of the above, tell him/her before you start taking PHARMACOR DIMETHYL FUMARATE.

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

There is no information on the use of Pharmacor Dimethyl Fumarate during pregnancy. Your doctor will discuss the risks and benefits of taking it if you are pregnant.

Check with your doctor if you are pregnant or intend to become pregnant.

If you plan to become pregnant, your treatment should be timed so that you have completed the course before becoming pregnant.

Talk to your doctor if you are breastfeeding or intend to breast-feed.

It is not known whether Pharmacor Dimethyl Fumarate passes into breast milk. Your doctor will discuss the risks and benefits of taking it if you are breastfeeding.

If you have not told your doctor about any of the above, tell them before you start taking Pharmacor Dimethyl Fumarate.

3. What if I am taking other medicines?

Tell your doctor if you have previously taken or are currently taking medicines containing fumaric acid (creams or tablets/ capsules).

You should not take Pharmacor Dimethyl Fumarate together with these medicines.

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

Some medicines and Pharmacor Dimethyl Fumarate may interfere with each other. These include:

- 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.

These medicines may be affected by Pharmacor Dimethyl Fumarate 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 PHARMACOR DIMETHYL FUMARATE?

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

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

How to take it

Swallow each capsule whole a glass of water. Do not crush, divide or dissolve the capsule or its contents.

When to take it

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.

Pharmacor Dimethyl Fumarate can be taken with or without food. For those patients who experience gastrointestinal side effects or flushing, taking Pharmacor Dimethyl Fumarate with food may help reduce these effects.

Your doctor may tell you to take Pharmacor Dimethyl Fumarate with aspirin or may temporarily reduce your dose.

Do not reduce your dose unless your doctor tells you to.

How long 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 Pharmacor Dimethyl Fumarate 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 Pharmacor Dimethyl Fumarate unless your doctor tells you to.

If you forget to take it

If it is almost time for your next dose (less than 6 hours before 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 use too much PHARMACOR DIMETHYL FUMARATE

If you think that you have used too much PHARMACOR DIMETHYL FUMARATE, 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.

Take your capsules with you to hospital.

5. What should I know while using PHARMACOR DIMETHYL FUMARATE

Things you should do

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

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

Before you start Pharmacor Dimethyl Fumarate, 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 Pharmacor Dimethyl Fumarate, 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. Pharmacor Dimethyl Fumarate may cause proteins (such as albumin) to be detected in a urine test.

Pharmacor Dimethyl Fumarate may also cause increases in the level of liver enzymes that will show up in a blood test.

Take Pharmacor Dimethyl Fumarate 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 Pharmacor Dimethyl Fumarate.

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.

Things you should not do

- Do not take PHARMACOR DIMETHYL FUMARATE to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they are also trying to stop smoking.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Tell your doctor straight away if you think you have an infection, have fever, or feel like you have the flu.

Pharmacor Dimethyl Fumarate may decrease lymphocyte (white blood cell) counts. White blood cells fight infection. You may get infections more easily while you are taking

Pharmacor Dimethyl Fumarate. 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 Pharmacor Dimethyl Fumarate until you recover.

Tell your doctor straight 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.

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 a low white blood cell count for a long period of time may increase your risk of PML.

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

Before you start Pharmacor Dimethyl Fumarate, 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 Pharmacor Dimethyl Fumarate, 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. Pharmacor Dimethyl Fumarate may cause proteins (such as albumin) to be detected in a urine test.

Looking after your medicine

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

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.

Store in original packaging in order to protect from light. Store below 25°C.

Do not store Pharmacor Dimethyl Fumarate or any in the

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

Heat and dampness can destroy some medicines

**Keep it where young children cannot reach it.
Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of

date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or when your doctor tells you to stop taking PHARMACOR DIMETHYL FUMARATE

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PHARMACOR DIMETHYL FUMARATE

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Common side effects

Common 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). 	<p>Tell your doctor or pharmacist if you notice any of the following and they worry you</p>

The above list includes the more common side effects of your medicine. If any of these persist or worsen, talk to your doctor as they may also be due to an infection or allergic reaction.

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>Call your doctor straight away if you notice any of these serious side effects.</p> <p>You may require medical attention.</p>

Very serious side effects

Very serious side effects	What to do
<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, 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 PHARMACOR DIMETHYL FUMARATE and call your doctor straightaway, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>You may need urgent medical attention or hospitalisation.</p>

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 PHARMACOR DIMETHYL FUMARATE contains

Active ingredient (main ingredient)	Dimethyl fumarate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Silicified microcrystalline cellulose • Croscarmellose sodium • Purified Talc

Who distributes PHARMACOR DIMETHYL FUMARATE

Pharmacor Pty Limited
Suite 803, Level 8
Tower A, The Zenith
821 Pacific Highway
CHATSWOOD, NSW, 2067
Australia

This leaflet was prepared in 09/2022

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| | <ul style="list-style-type: none">• Colloidal anhydrous silica• Magnesium stearate• Eudragit L100 (Methacrylic acid copolymer)• Triethyl citrate• Isopropyl alcohol• Eudragit L30D-55 (Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion)• FD&C BLUE2• Iron Oxide yellow• Titanium dioxide• Gelatin |
|--|---|

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

What PHARMACOR DIMETHYL FUMARATE looks like

PHARMACOR DIMETHYL FUMARATE is available in 2 strengths:

- Pharmacor Dimethyl Fumarate 120 mg Delayed Release Capsules- White to off white, enteric coated round shaped mini tablets filled in size "1" hard gelatin capsules, Opaque Green cap printed with "DMF" and Opaque white body printed with "120" in black ink.
Pharmacor Dimethyl Fumarate 120 mg Delayed Release Capsules are supplied in PVC-PVDC aluminium blister packs, in pack sizes of 14's, 70's, 112's.
- Pharmacor Dimethyl Fumarate 240 mg Delayed Release Capsules- White to off white, enteric coated round shaped mini tablets filled in size "0" hard gelatin capsules, Opaque Green cap printed with "DMF" and Opaque green body printed with "240" in black ink. The following packs are available:
Pharmacor Dimethyl Fumarate 240 mg Delayed Release Capsules are supplied in PVC-PVDC aluminium blister packs, in pack sizes of 14's, 56's, 70's, 112's.

Australian Registration Numbers

PHARMACOR Dimethyl Fumarate - dimethyl fumarate 240 mg delayed release capsule blister pack (309591)

PHARMACOR Dimethyl Fumarate - dimethyl fumarate 120 mg delayed release capsule blister pack (309592)