

TECFIDERA®

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 TECFIDERA?

TECFIDERA contains the active ingredient dimethyl fumarate. TECFIDERA is used to decrease the inflammation in the brain that is caused by multiple sclerosis (MS) and thereby reduces nerve damage.

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

2. What should I know before I use TECFIDERA?

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

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

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 TECFIDERA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TECFIDERA 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 TECFIDERA?

- The recommended starting dose of TECFIDERA is one capsule of 120 mg taken twice daily. After 7 days the recommended dose is one capsule of 240 mg taken twice daily.
- Swallow each capsule whole with a glass of water. Do not crush, divide or dissolve the capsule.
- TECFIDERA can be taken with or without food.

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

5. What should I know while using TECFIDERA?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are using TECFIDERA.● Check with your doctor if you have any medical conditions such as: 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.
Things you should not do	<ul style="list-style-type: none">● Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.● Do not take TECFIDERA 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 TECFIDERA affects you.
Drinking alcohol	<ul style="list-style-type: none"> ● Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> ● Keep your capsules in the pack until it is time to take them. ● Keep your capsules in a cool dry place away from light where the temperature stays below 30°C.

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

6. Are there any side effects?

Common side effects include: reddening of the face or body feeling warm or itchy, diarrhoea, stomach pain or cramps, inflammation of the lining of the intestines or stomach, nausea or vomiting, indigestion, rash, pink or red blotches on the skin, hair thinning and runny nose.

Serious adverse events include infections and allergic reactions.

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.

TECFIDERA

Active ingredient(s): dimethyl fumarate

Consumer Medicine Information (CMI)

This leaflet provides important information about using TECFIDERA. **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 TECFIDERA.**

Where to find information in this leaflet:

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

1. Why am I using TECFIDERA?

TECFIDERA contains the active ingredient dimethyl fumarate.

Dimethyl fumarate decreases the inflammation in your brain that is caused by multiple sclerosis (MS) and thereby reduces nerve damage.

TECFIDERA 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.

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

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

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.

TECFIDERA 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.

2. What should I know before I use TECFIDERA?

Warnings

Do not use TECFIDERA 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.

Check with your doctor if you:

- have any other medical conditions such as:
 - 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 have allergies to any other medicines, foods, preservatives or dyes.

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

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

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

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

There is no information on the use of TECFIDERA 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 TECFIDERA passes into breast milk. Your doctor will discuss the risks and benefits of taking it if you are breast-feeding.

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.

- medicines containing fumaric acid (creams or tablets/capsules). You should not take TECFIDERA together with these medicines.
- 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) and certain types of painkillers (such as ibuprofen and other similar anti-inflammatory medicines including medicines purchased without a doctor's prescription).
- medicines that contain lithium
- live vaccines.

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

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

4. How do I use TECFIDERA?

How much to take

- Follow the instructions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.
- Use TECFIDERA until your doctor tells you to stop.
- The recommended starting dose of TECFIDERA is 120 mg taken twice daily. After 7 days the recommended dose is 240 mg twice daily.
- Do not reduce your dose unless your doctor tells you to.
- This medicine helps to control your condition, but does not cure it. The positive effects of TECFIDERA 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 TECFIDERA unless your doctor tells you to.

When to take TECFIDERA

- Take one TECFIDERA capsule twice a day.
- Swallow each capsule whole with a glass of water. Do not crush, divide or dissolve the capsule or its contents.
- 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.
- TECFIDERA can be taken with or without food. For those patients who experience gastrointestinal side effects or flushing, taking TECFIDERA with food may help reduce these effects.
- Your doctor may tell you to take TECFIDERA with aspirin or may temporarily reduce your dose.

If you forget to use TECFIDERA

TECFIDERA should be used regularly at the same time each day. If you miss your dose at the usual time:

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 have trouble remembering to take your medicine, Ask your pharmacist for some hints.

If you use too much TECFIDERA

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

You should immediately:

- phone the Poisons Information Centre
- **(by calling in Australia telephone 13 11 26, in New Zealand telephone 0800 POISON or 0800 764 766), 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 using TECFIDERA?

Things you should do

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

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

- Take TECFIDERA 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 TECFIDERA.

Call your doctor straight away if you:

- If you become pregnant while taking TECFIDERA.
- Remind any doctor, dentist or pharmacist you visit that you are using TECFIDERA.

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.
- Do not take TECFIDERA 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.

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.**
- TECFIDERA may decrease lymphocyte (white blood cell) counts. White blood cells fight infection. You may get infections more easily while you are taking

- **TECFIDERA.** 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 TECFIDERA 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 low lymphocyte levels, particularly for a long period of time, can increase your risk of PML.
- **Keep all of your doctor's appointments so that your progress can be checked.**
 - Before you start TECFIDERA, 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 TECFIDERA, 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. TECFIDERA may cause proteins (such as albumin) to be detected in a urine test.
 - TECFIDERA may cause increases in the level of liver enzymes that will show up in a blood test.

- TECFIDERA may also cause liver inflammation and increase in levels of liver enzymes (ALT or AST in combination with bilirubin).

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Keep your capsules in a cool dry place away from light where the temperature stays below 30°C.

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 window sills or in the car.
- 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.

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>Vascular-related:</p> <ul style="list-style-type: none">• reddening of the face or body feeling warm, hot, burning or itchy (flushing) <p>Digestion system related:</p> <ul style="list-style-type: none">• loose stools (diarrhoea)• gastrointestinal disorder	<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"> ● stomach pain or stomach cramps ● feeling sick (nausea) ● being sick (vomiting) ● indigestion (dyspepsia) ● inflammation of the lining of the intestines (gastroenteritis) ● inflammation of the lining of the stomach (gastritis) <p>Skin-related:</p> <ul style="list-style-type: none"> ● itchy skin (pruritus) ● rash ● pink or red blotches on the skin (erythema) ● hair thinning <p>Respiratory-related:</p> <ul style="list-style-type: none"> ● runny nose (rhinorrhoea) <p>Non-specific effect on the body:</p> <ul style="list-style-type: none"> ● burning sensation ● hot flush, feeling hot 	

Serious side effects

Serious side effects	What to do
<p>Infection-related:</p> <ul style="list-style-type: none"> • signs of infection (e.g., unexplained fever, severe diarrhoea). 	<p>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>
<p>Allergic reaction related</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 <p>Infection-related:</p> <p>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>	<p>These are very serious side effects. You may need urgent medical attention or hospitalisation. Stop taking TECFIDERA and tell your doctor immediately or go to Emergency at your nearest hospital.</p> <p>These side effects are very rare.</p>

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 TECFIDERA 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)
methylacrylate-methyl
methacrylate copolymer
methacrylic acid-ethyl
acrylate copolymer
simethicone
sodium lauryl sulfate
(E514)
polysorbate 80 (E433)
gelatin
titanium dioxide (E171)
brilliant blue FCF CI42090
(E133)
iron oxide yellow CI77492
(E172)
iron oxide black CI77499
(E172).

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

What TECFIDERA looks like

TECFIDERA capsules are available in two strengths: 120 mg and 240 mg.

The 120 mg capsules are green and white printed with 'BG-12, 120 mg' in black ink on the capsule body. Available in blister wallet cards containing 14 or 112 capsules packed in a box.

The 240 mg capsules are green printed with 'BG-12, 240 mg' in black ink on the capsule body. Available in blister wallet cards containing 14 or 56 capsules packed in a box.

Not all pack sizes may be available.

TECFIDERA 120 mg - AUST R 197118

TECFIDERA 240 mg - AUST R 197119

Further information

You can obtain more information from your doctor, pharmacist or nurse or by telephoning 1800 852 289 in Australia or 0800 852 289 in New Zealand.

Who distributes TECFIDERA

TECFIDERA is supplied in Australia by:

Biogen Australia Pty Ltd Level 4, 2 Banfield Road
Macquarie Park NSW 2113

TECFIDERA is supplied in New Zealand by:

Biogen NZ Biopharma Limited

188 Quay Street, Auckland

This leaflet was prepared in May 2026.