

TRAZENT

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 TRAZENT?

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

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

2. What should I know before I take TRAZENT?

Do not take if you have ever had an allergic reaction to TRAZENT 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 TRAZENT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TRAZENT 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 TRAZENT?

- Your doctor will tell you how many capsules to take and how often you should take them.
- It is important to keep taking your medicine even if you feel well.

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

5. What should I know while taking TRAZENT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using TRAZENT• If you are about to have any blood or urine tests, tell your doctor that you are taking TRAZENT.• Tell your partner or caregiver about your treatment.• Tell your doctor if you are going to be vaccinated.
Things you should not do	<ul style="list-style-type: none">• Do not take TRAZENT to treat any other complaints unless your doctor tells you to.• Do not stop taking your medicine or lower the dosage without checking with your doctor.
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 25°C.

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

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 TRAZENT. Tell your doctor immediately or go to the Emergency Department at your nearest hospital if you notice any signs of infection (e.g., unexplained fever, severe diarrhoea), 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.

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.

TRAZENT

Active ingredient(s): *dimethyl fumarate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using TRAZENT. **You should also speak to your doctor or pharmacist or the MS Society in your State, or by telephoning the MS Alliance on 1800 852 289 in Australia or 0800 852 289 if you would like further information or if you have any concerns or questions about using TRAZENT.**

Where to find information in this leaflet:

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

1. Why am I taking TRAZENT?

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

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

TRAZENT 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.

TRAZENT 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.

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

2. What should I know before I take TRAZENT

Warnings

Do not take TRAZENT 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 take 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.

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

Tell your doctor at your earliest opportunity if you suspect you have any symptoms of shingles. If you are not sure whether you should start taking this medicine, talk to your doctor.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

There is no information on the use of TRAZENT during pregnancy.

Your doctor will discuss the risks and benefits of taking it if you are pregnant.

It is not known whether TRAZENT 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.

Tell your doctor or pharmacist if you are taking medicines containing fumaric acid (creams or tablets/ capsules),

Some medicines may interfere with TRAZENT and affect how it works.

- 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 TRAZENT 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.

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

4. How do I take TRAZENT?

How much to take

- The recommended starting dose of TRAZENT is 120 mg taken twice daily. After 7 days the recommended dose is 240 mg twice daily.
- Follow the instructions provided and use TRAZENT until your doctor tells you to stop.
- This medicine helps to control your condition but does not cure it. The positive effects of TRAZENT 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 TRAZENT unless your doctor tells you to.

When to take TRAZENT

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.

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

Your doctor may tell you to take TRAZENT with aspirin or may temporarily reduce your dose.

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

How to take TRAZENT

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

If you forget to take TRAZENT

TRAZENT should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

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 take too much TRAZENT

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 TRAZENT?

Things you should do

- **If you are about to have any blood or urine tests, tell your doctor that you are taking TRAZENT.**
- Blood and urine test results may be affected by treatment with TRAZENT.
- Before you start TRAZENT, 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 TRAZENT, 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. TRAZENT may cause proteins (such as albumin) to be detected in a urine test.
- TRAZENT may also cause increases in the level of liver enzymes that will show up in a blood test.
- Take TRAZENT 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 TRAZENT.
- 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.

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

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

Call your doctor straight away if you:

- think you have an infection, have fever, or feel like you have the flu.
- TRAZENT may decrease lymphocyte (white blood cell) counts. White blood cells fight infection. You may get

infections more easily while you are taking TRAZENT.

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

Things you should not do

Do not take TRAZENT 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.

Avoid consumption of alcohol for at least one hour after taking TRAZENT, as alcohol may lead to increased frequency of gastrointestinal adverse reactions.

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 25°C.

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; for example, do not store it:

- 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.

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

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
<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. 	<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>

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, or go straight to the Emergency Department at your nearest hospital 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, new or worsening weakness on one side of the body; clumsiness; changes in vision, thinking, or memory; or confusion or personality changes. 	<p>If any of the following happen, stop taking TRAZENT and tell your doctor immediately or go to Emergency at your nearest hospital.</p> <p>The above list includes very serious side effects.</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.

14 or 56 capsules packed in a box. Not all pack sizes may be sold.

Who distributes TRAZENT

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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7. Product details

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

What TRAZENT contains

Active ingredient (main ingredient)	Dimethyl fumarate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Silicified microcrystalline cellulose• Purified talc• Croscarmellose sodium• Colloidal anhydrous silica• Magnesium stearate• Methacrylic Acid Copolymer• Triethyl citrate• Methacrylic acid - ethyl acrylate copolymer (1:1)• Gelatin• Titanium Dioxide• FD&C Blue 1• Iron Oxide Black• Iron Oxide Yellow• Capsules also contain trace of TekPrint SW 9008 Black ink (ARTG No:2328).

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

TRAZENT capsules contains sulfites.

What TRAZENT looks like

TRAZENT comes in two strengths of capsules:

- 120 mg (AUST R 309021): Size "0" hard gelatin capsules with green cap and white body, printed with "HR1" in black ink on capsule body containing white to off-white, round, biconvex enteric coated mini tablets plain on both the sides.

Approved in blisters containing 7,

14 or 112 capsules packed in a box.

- 240 mg (AUST R 309022): Size "0" hard gelatin capsules with green cap and body, printed with "HR2" in black ink on capsule body containing white to off-white, round, biconvex enteric coated mini tablets plain on both the sides.

Approved in blisters containing 7,