

Teriflunomide Devatis

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 Teriflunomide Devatis?

Teriflunomide Devatis contains the active ingredient teriflunomide. Teriflunomide Devatis is used to treat relapsing forms of multiple sclerosis (MS).

For more information, see Section 1. Why am I using Teriflunomide Devatis? in the full CMI.

2. What should I know before I use Teriflunomide Devatis?

Do not use if you have ever had an allergic reaction to teriflunomide, leflunomide 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 Teriflunomide Devatis? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Teriflunomide Devatis 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 Teriflunomide Devatis?

- Follow all directions given to you by your doctor and pharmacist carefully. The usual dose for this medicine is one 14 mg tablet per day. Swallow the tablet whole with a glass of water.

More instructions can be found in Section 4. How do I use Teriflunomide Devatis? in the full CMI.

5. What should I know while using Teriflunomide Devatis?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Teriflunomide Devatis.If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.
Things you should not do	<ul style="list-style-type: none">Do not stop taking Teriflunomide Devatis, or lower the dose, without checking with your doctor.
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 Teriflunomide Devatis affects you.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you drink alcohol. The effects of alcohol could be made worse while taking Teriflunomide Devatis. It is recommended that you minimise your alcohol intake while taking Teriflunomide Devatis.
Looking after your medicine	<ul style="list-style-type: none">Keep the medicine in a cool dry place. Store at or below 25°C.Keep your tablets in the container until it is time to take them.

Teriflunomide Devatis 14 mg Film Coated Tablets

Each film coated tablet contains 14 mg Teriflunomide

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Teriflunomide Devatis.

This leaflet answers some common questions about Teriflunomide Devatis. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Teriflunomide Devatis against the benefits they expect it will have for you.

If you have any questions about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

Where to find information in this leaflet:

- 1. Why am I using Teriflunomide Devatis?**
 - 2. What should I know before I use Teriflunomide Devatis?**
 - 3. What if I am taking other medicines?**
 - 4. How do I use Teriflunomide Devatis?**
 - 5. What should I know while using Teriflunomide Devatis?**
 - 6. Are there any side effects?**
 - 7. Product details**
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1. Why am I using Teriflunomide Devatis?

Teriflunomide Devatis contains the active ingredient teriflunomide.

Teriflunomide Devatis is used to treat relapsing forms of multiple sclerosis (MS).

The cause of MS is not yet known. MS affects the central nervous system (CNS) - the brain and spinal cord.

In MS, the body's immune system reacts against its own myelin (the 'insulation' or the protective sheath surrounding nerve fibres). With relapsing forms of MS, people can have repeated attacks or relapses of inflammation of the CNS from time to time.

Symptoms vary from patient to patient and may include blurred vision, weakness in the legs or arms, or loss of control of bowel or bladder function. These are followed by periods of recovery.

Teriflunomide Devatis works by selectively interfering with the ability of white blood cells (lymphocytes) to produce the disease response and nerve damage that ultimately leads to relapses.

Teriflunomide has been shown to reduce or decrease the number of relapses and slow down the progression of physical disability in patients with relapsing forms of MS. Although it is not a cure, patients treated with teriflunomide generally find they will have fewer relapses.

Your doctor, however, may have prescribed Teriflunomide Devatis for another purpose.

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

2. What should I know before I use Teriflunomide Devatis

Warnings

Do not use Teriflunomide Devatis if:

- you are allergic to teriflunomide, leflunomide or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- have any diseases which reduce your body's natural defences
- have any diseases of the blood
- have, or have had any serious skin disorders such as rash with blisters and peeling of the skin or extended rashes with the liver, blood and other body organs involvement
- have severe liver disease
- have a condition called hypoproteinaemia (when you do not have enough protein in your blood)
- are pregnant or plan to become pregnant
- are not using reliable birth control
- are breastfeeding

Before you start to take it

Check with your doctor if you:

- intend to become pregnant or father a child.
- have any other medical conditions especially the following: Liver problems, high blood pressure, chronic or serious infection, a decrease in the number of white blood cells or an illness which lowered your body's resistance to disease, tuberculosis, lung problems, such as interstitial lung disease (an inflammation of lung tissue) which is a serious and potentially fatal disease, or kidney disease

Before you start Teriflunomide Devatis, your doctor will need to take blood samples to check the health of your liver and blood cells. This must be done in the last 6 months before starting this medicine.

Tell your doctor if you plan to have surgery.

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

You must not become pregnant while taking Teriflunomide Devatis and for a certain period of time after stopping Teriflunomide Devatis.

Teriflunomide Devatis may increase the risk of birth defects. To reduce any risk to the developing baby, you will need to stop taking Teriflunomide Devatis and may need to undergo a wash-out procedure. Your doctor will discuss the wash-out procedure with you.

Women of childbearing potential must use reliable contraception while taking Teriflunomide Devatis.

Tell your doctor immediately if you think you could be pregnant while taking Teriflunomide Devatis.

Tell your doctor if you intend to become pregnant or father a child.

Do not take it if you are breastfeeding or planning to breastfeed.

Teriflunomide passes into breast milk and there is a serious risk to the baby. You and your doctor will decide what is best for you and your baby.

Children and adolescents

Do not give Teriflunomide Devatis to a child or adolescent

Teriflunomide Devatis is not approved for use in children or adolescents under 18 years old.

3. What if I am taking other 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 may interfere with Teriflunomide Devatis and affect how it works or be affected by Teriflunomide Devatis.

Interactions between teriflunomide and other medications include:

- Some antibiotics such as rifampicin, cefaclor, penicillin G and ciprofloxacin
- Some medicines used to treat epilepsy such as carbamazepine and phenytoin
- Some medicines used for diabetes such as repaglinide or pioglitazone
- Some medicines to treat cancer such as paclitaxel, doxorubicin, methotrexate
- Some medicines used to treat depression such as duloxetine
- Ondansetron, a medicine used to prevent and treat nausea
- Theophylline, a medicine used to prevent asthma
- Warfarin, a medicine used to prevent blood clots
- Some medicines used to lower cholesterol such as “statins” - rosuvastatin
- St John's Wort

You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

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

In certain situations, for example, if you experience a serious side effect, you change your medication or you want to fall pregnant, your doctor will ask you to take medication that will help your body get rid of Teriflunomide Devatis faster.

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

4. How do I use Teriflunomide Devatis

How much to take

- The usual dose for this medicine is one 14 mg tablet per day.
- Your doctor may have prescribed a different dose.
- Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.
- Follow the instructions they give you. These directions may differ from the information contained in this

leaflet. If you take the wrong dose, Teriflunomide Devatis may not work as well.

- Continue taking your medicine for as long as your doctor or pharmacist tells you.

The medicine helps control your condition, but it does not cure it. Therefore, you must take it every day.

When to take Teriflunomide Devatis

- Teriflunomide Devatis should be taken at about the same time every day. Taking your tablets at the same time each day will have the best effect. It will also help you to remember when to take the tablets.
- It does not matter if you take Teriflunomide Devatis before or after food

How to take Teriflunomide Devatis

- Swallow the tablet whole with a full glass of water.

If you forget to use Teriflunomide Devatis

Teriflunomide Devatis should be used regularly at the same time each day.

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 there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

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

If you use too much Teriflunomide Devatis

If you think that you or anyone else may have used too much Teriflunomide Devatis, you may need urgent medical attention.

Immediately telephone your doctor or Poisons Information Centre (In New Zealand telephone 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Teriflunomide Devatis. Do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Teriflunomide Devatis

Things you should do

If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.

If you need to stop treatment, the levels of Teriflunomide Devatis in your blood can be lowered rapidly using a special wash-out procedure.

If you are female talk to your doctor about birth control that you must use during treatment. You must use reliable methods of birth control while taking Teriflunomide Devatis.

Talk to your doctor if you plan to become pregnant or before you stop taking this medicine.

Tell your doctor if you need to have a vaccination during treatment with this medicine or for 6 months after stopping treatment.

Call your doctor straight away if you:

- have an infection or notice chills or a fever or signs of an infection while taking this medicine
- your skin becomes itchy or yellow, the whites of your eyes become yellow, you start to bleed or bruise easily, or your urine becomes very dark or you have stomach pain, nausea or vomiting, stop taking it immediately. You may be developing a liver problem
- experience numbness or tingling in the hands or feet or numbness or weakness of the arms and legs

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

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Teriflunomide Devatis.

Things you should not do

- Do not take more than the recommended dose unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Teriflunomide Devatis, or lower the dose, without checking with your doctor.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

The effects of alcohol could be made worse while taking Teriflunomide Devatis. It is recommended that you minimise your alcohol intake while taking Teriflunomide Devatis.

Looking after your medicine

- Keep the medicine in a cool dry place. Store at or below 25°C.
- Keep your tablets in the container until it is time to take them.

Follow the instructions on 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.

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	What to do
<ul style="list-style-type: none"> • Diarrhoea • Rashes, itchy skin • Hair loss • Weight loss • Unusual tiredness or weakness • Numbness or tingling of hands or feet • Thickened, inflamed, red patches on the skin, which may be accompanied with whitish scaly skin, or accompanied by white pus-filled bumps • Nail disorders 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • Signs and symptoms of severe infection e.g fever • Severe upper stomach pain, often with nausea and vomiting • Severe skin rash or sores in your mouth • Your skin becomes pale, you start to feel tired, you become prone to infections or bruising • If you develop new or worsening symptoms such as cough or trouble breathing, with or without a fever • Inflammation of the colon, symptoms include diarrhea usually with blood and mucus <p>Allergic reaction:</p> <ul style="list-style-type: none"> • Swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing • Hives • Fainting • Yellowing of the skin and eyes (jaundice) • Thickened patches of red skin 	<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>

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Centre for Adverse Reactions Monitoring (CARM) within the New Zealand Pharmacovigilance Centre <https://nzphvc.otago.ac.nz/reporting/>.

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 Teriflunomide Devatis contains

Active ingredient (main ingredient)	Teriflunomide 14 mg
Other ingredients	<u>Tablet core</u> Lactose monohydrate, Milled Maize starch Cellulose, microcrystalline, PH 101 Hydroxypropylcellulose, Type EXF Sodium starch glycolate, Type A Silica, colloidal anhydrous Magnesium stearate Purified water <u>Film coating</u> HPMC 2910/Hypromellose (E464) Titanium Dioxide (E171) Triacetin FD&C BLUE #2/Indigo Carmine AL 3% - 5% (E132)

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

What Teriflunomide Devatis looks like

Teriflunomide Devatis 14 mg film coated tablets are pale blue to pastel blue, biconvex, round (approximately 6 mm diameter), film-coated tablets.

The finished product is packed in blister packs of OPA/Aluminium/PVC sealed with aluminium foil.

Teriflunomide Devatis 14 mg film coated tablets are supplied in blister packs of 5, 10, 14, 28 or 84 tablets.

Who distributes Teriflunomide Devatis

DEVATIS LIMITED

Findex, 173 Spey Street, Invercargill 9810,

New Zealand

Toll Free Number: 0800 887750

www.devatis.nz

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