

Teriflunomide Sandoz®

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 Sandoz?

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

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

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

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

3. What if I am taking other medicines?

Some medicines may interfere with Teriflunomide Sandoz 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 Sandoz?

- 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 tablet whole with a glass of water.

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

5. What should I know while using Teriflunomide Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Teriflunomide Sandoz.• 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 using this medicine, 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 Sandoz 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 Sandoz. It is recommended that you minimise your alcohol intake while taking Teriflunomide Sandoz.
Looking after your medicine	<ul style="list-style-type: none">• Keep the medicine in a cool dry place where the temperature stays below 30°C.• Keep your tablet in the container until it is time to take them.

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

6. Are there any side effects?

Less serious side effects include 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. More serious side effects include 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; skin becoming pale, you start to feel tired, you become prone to infections or bruising; new or worsening symptoms such as cough or trouble breathing, with or without a fever; feeling short of breath, tired, experiencing dizziness or fainting, have a blue tinge to your lips or skin, feeling pressure in your chest, have swelling around your ankles and legs, weight gain over a short period of time or abdominal bloating; inflammation of the colon, symptoms include diarrhoea usually with blood and mucus; allergic reaction such as 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.

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.

Teriflunomide Sandoz®

Active ingredient(s): *Teriflunomide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Teriflunomide Sandoz. **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 Teriflunomide Sandoz.**

Where to find information in this leaflet:

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

1. Why am I using Teriflunomide Sandoz?

Teriflunomide Sandoz contains the active ingredient teriflunomide.

Teriflunomide Sandoz 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 Sandoz 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 Sandoz 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 Sandoz generally find they will have fewer relapses.

Your doctor, however, may have prescribed Teriflunomide Sandoz 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 Sandoz?

Warnings

Do not use Teriflunomide Sandoz 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

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 Sandoz, 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 Sandoz and for a certain period of time after stopping Teriflunomide Sandoz.

Teriflunomide Sandoz may increase the risk of birth defects. To reduce any risk to the developing baby, you will need to stop taking Teriflunomide Sandoz 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 Sandoz.

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

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 Sandoz 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 Sandoz to a child or adolescent.

Teriflunomide Sandoz 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 medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Teriflunomide Sandoz and affect how it works or be affected by Teriflunomide Sandoz.

Interactions between Teriflunomide Sandoz 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 Sandoz.

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 Sandoz 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 Sandoz.

4. How do I use Teriflunomide Sandoz?

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 Sandoz 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 Sandoz

- Teriflunomide Sandoz 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 Sandoz before or after food.

How to take Teriflunomide Sandoz

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

If you forget to use Teriflunomide Sandoz

Teriflunomide Sandoz 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 Sandoz

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia), or (by calling 0800 764 766 in New Zealand), 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 Teriflunomide Sandoz?

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 Sandoz 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 Sandoz.

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 Sandoz.

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

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 Sandoz, 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 Sandoz affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Keep the medicine in a cool dry place where the temperature stays below 30°C.
- Keep your tablet in the container until it is time to take them.

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.

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
<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

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 of bruising• If you develop new or worsening symptoms such as cough or trouble breathing, with or without a fever• Feeling short of breath, tired, experiencing dizziness or fainting, have a blue tinge to your lips or skin, feeling pressure in your chest, have swelling around your ankles and legs, weight gain over a short period of time or abdominal bloating• Inflammation of the colon, symptoms include diarrhoea 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>

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 (Australia) or Centre for Adverse Reactions Monitoring (CARM) within the New Zealand Pharmacovigilance Centre <https://pophealth.my.site.com/carmreportnz/s/> (New Zealand). 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 Sandoz contains

Active ingredient (main ingredient)	teriflunomide 14 mg
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• maize starch• hypromellose• microcrystalline cellulose• sodium starch glycollate• colloidal anhydrous silica• magnesium stearate• hypromellose• glycerol• purified talc• titanium dioxide• indigo carmine aluminium lake• brilliant blue FCF aluminium lake• allura red AC aluminium lake• OPADRY® Blue 03M505004
Potential allergens	<ul style="list-style-type: none">• lactose monohydrate• sodium starch glycollate

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

What Teriflunomide Sandoz looks like

Teriflunomide Sandoz 14 mg tablets are blue coloured, round, bi-convex film coated tablets with "14" imprinted on one side. Teriflunomide Sandoz 14 mg tablets are supplied in blister packs of 28 tablets.

(AUST R 300684).

Who distributes Teriflunomide Sandoz

Teriflunomide Sandoz is supplied in Australia by:

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

Teriflunomide Sandoz is supplied in New Zealand by:

Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369

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