

Teriflunomide Sandoz®

Teriflunomide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Teriflunomide Sandoz.

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 Sandoz against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Teriflunomide Sandoz is used for

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.

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

Before you take it

When you must not take it

Do not take Teriflunomide Sandoz if you:

- have any diseases which reduce your body's natural defences
- have any diseases of the blood
- have any serious skin disorders
- 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

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.

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

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

Teriflunomide Sandoz passes into the breast milk and therefore there is a possibility that the breastfed baby may be affected.

Do not take Teriflunomide Sandoz if you are allergic to teriflunomide, leflunomide or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

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.

Do not take it after the expiry date (exp) printed on the pack.

Do not take it if the packaging is torn or shows signs of tampering.

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

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- leflunomide or any of the ingredients listed at the end of this leaflet
- Any other substances, such as foods, preservatives or dyes

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.

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.

You should not breastfeed while you are taking Teriflunomide Sandoz. Teriflunomide Sandoz can pass 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.

Tell your doctor if you have or have had any 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
- 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.

If you have not told your doctor about any of the above, tell them before you take Teriflunomide Sandoz.

Taking other medicines

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

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

These medicines may be affected by Teriflunomide Sandoz, or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines. Your doctor or pharmacist will advise you.

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.

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

How to take it

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

They may differ from the information contained in this leaflet.

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

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.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

It does not matter if you take Teriflunomide Sandoz before or after food.

Take Teriflunomide Sandoz at about the same time each 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.

If you are not sure when to take it, ask your doctor or pharmacist.

How long to take it

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.

Ask your doctor or pharmacist if you are not sure how long to take the medicine for.

If you forget to take it

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia 13 11 26 or New Zealand 0800 poison or 0800 764766), or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too much Teriflunomide Sandoz.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists or other healthcare providers who are treating you that you are taking Teriflunomide Sandoz.

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

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 immediately

- If you have an infection or notice chills or a fever or signs of an infection while taking this medicine
- If 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.
- If you experience numbness or tingling in the hands or feet or numbness or weakness of the arms and legs

Your doctor may need to take blood samples to monitor the health of your liver and blood cells while you are taking Teriflunomide Sandoz.

Tell your doctor if you need to have a vaccination during

treatment with this medicine or for 6 months after stopping treatment.

Things you must 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.

Things to be careful of

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.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Teriflunomide Sandoz.

Teriflunomide Sandoz helps most people with relapsing forms of MS, but it may have unwanted side effects although not everybody gets them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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.

These are the more common side effects of Teriflunomide Sandoz.

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following:

- 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

These may be serious side effects of Teriflunomide Sandoz and you may need urgent medical attention.

Serious side effects are uncommon.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to accident and emergency at your nearest hospital:

- 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

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Teriflunomide Sandoz. You may

need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Some people may have other side effects not yet known or mentioned in this leaflet.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

Storage

Keep your tablets in the container until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

Keep the medicine in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

Disposal

If your doctor or pharmacist tells you to stop taking Teriflunomide Sandoz or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it 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.

Ingredients

Active ingredients:

Each tablet contains 14 mg of the active ingredient, teriflunomide.

Inactive ingredients:

Lactose monohydrate

Maize starch

Hypromellose

Microcrystalline cellulose

Sodium starch glycollate

Colloidal anhydrous silica

Magnesium stearate

Hypromellose

Glycerol

Purified talc and titanium dioxide

Indigo carmine aluminium lake

Brilliant blue FCF aluminium lake

Allura red AC aluminium lake

OPADRY® Blue 03M505004

Manufacturer/sponsor

Teriflunomide Sandoz is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park
NSW 2113
Tel: 1800 726 369

Australian registration number(s):

Teriflunomide Sandoz 14 mg
AUST R 300684.

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