

# TERIMIDE®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

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### 1. Why am I taking TERIMIDE?

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

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

### 2. What should I know before I take TERIMIDE?

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

### 3. What if I am taking other medicines?

Some medicines may interfere with TERIMIDE 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 TERIMIDE?

- The usual dose for this medicine is one 14 mg tablet per day. Your doctor may have prescribed a different dose.
- Swallow the tablets whole with a full glass of water. More instructions can be found in Section [4. How do I take TERIMIDE?](#) in the full CMI.

### 5. What should I know while taking TERIMIDE?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking TERIMIDE.
- If you become pregnant while taking this medicine, stop taking it

	<p>and tell your doctor or pharmacist immediately.</p> <ul style="list-style-type: none"> <li>• For men taking TERIMIDE, tell your doctor if your female partner plans to become pregnant.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop taking your medicine or lower the dosage without checking with your doctor.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how TERIMIDE affects you.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• The effects of alcohol could be made worse while taking TERIMIDE. It is recommended you minimise your alcohol intake while taking this medicine.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your tablets in a cool dry place where the temperature stays below 25°C.</li> <li>• Keep your tablets in the pack until it is time to take them.</li> </ul>

For more information, see Section [5. What should I know while taking TERIMIDE?](#) 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.

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; 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.

**This is not a complete list of all possible side effects.** 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.

# TERIMIDE®

**Active ingredient(s):** *teriflunomide*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking TERIMIDE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking TERIMIDE.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking TERIMIDE?

TERIMIDE contains the active ingredient teriflunomide.

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

This medicine belongs to a group of medicines called immunomodulating drugs.

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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.

This medicine 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.

TERIMIDE 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 TERIMIDE generally find they will have fewer relapses.

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.

## 2. What should I know before I take TERIMIDE?

### Warnings

#### Do not take TERIMIDE if:

- you are allergic to teriflunomide, any other similar medicines or any of the ingredients listed at the end of this leaflet. 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

Always check the ingredients to make sure you can take this medicine.

- you have allergies to any other medicines, foods, preservatives or dyes.
- any diseases which reduce your body's natural defences
- any diseases of the blood
- 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
- severe liver disease
- a condition called hypoproteinaemia (when you do not have enough protein in your blood)

- you are not using reliable birth control
- you are pregnant or planning to become pregnant
- you are breastfeeding

### **Check with your doctor if you:**

- intend to become pregnant
- are male and your female partner plans to become pregnant
- 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 TERIMIDE, 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 TERIMIDE and for a certain period of time after stopping TERIMIDE.**

TERIMIDE may increase the risk of birth defects. To reduce any risk to the developing baby, you will need to stop taking TERIMIDE and may need to undergo a wash-out procedure to rapidly lower TERIMIDE levels in your blood. Your doctor will discuss the wash-out procedure with you.

**Do not take this medicine if you are not using reliable birth control.**

**Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.**

It may affect your developing baby if you take it during pregnancy.

The active ingredient in TERIMIDE passes into breast milk and there is a possibility that your baby may be affected.

## **For men taking TERIMIDE**

**TERIMIDE can be detected in your semen.**

**Tell your doctor if your female partner plans to become pregnant.**

**To reduce the risk of birth defects, if your female partner:**

- plans to become pregnant, talk to your doctor before you stop taking this medicine and ask your doctor how to rapidly lower the levels of TERIMIDE in your blood before she becomes pregnant.
- does not plan to become pregnant, you and your partner should use reliable birth control during your treatment with TERIMIDE. TERIMIDE remains in your blood after you stop taking it, so continue using reliable birth control until TERIMIDE blood levels have been checked and are low enough.

## **Children and adolescents**

**Do not give this medicine to a child under the age of 18 years.**

Safety and effectiveness in children younger than 18 years have not been established.

### **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 TERIMIDE and affect how it works or be affected by TERIMIDE.**

Interactions between TERIMIDE and other medications include:

- antibiotics such as rifampicin, cefaclor, penicillin G and ciprofloxacin

- medicines used to treat epilepsy such as carbamazepine and phenytoin
- some medicines used for diabetes such as repaglinide or pioglitazone
- some medicines used 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 treat asthma
- warfarin, a medicine used to prevent blood clots
- some medicines used to lower cholesterol such as statins, rosuvastatin
- St. John's Wort (*Hypericum perforatum*)

You may need different amounts of your medicines, or you may need to take different medicines.

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 TERIMIDE faster.

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 TERIMIDE.**

## 4. How do I take TERIMIDE?

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

- Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

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

### When to take TERIMIDE

- Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- It does not matter if you take this medicine before or after food.

### How to take TERIMIDE

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

## **If you forget to take TERIMIDE**

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

## **If you take too much TERIMIDE**

If you think that you or anyone else may have taken too much TERIMIDE, urgent medical attention may be needed.

**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 TERIMIDE?**

### **Things you should do**

- **If you become pregnant while taking this medicine, stop taking it and tell your doctor immediately.**
- **If you need to stop treatment, the levels of TERIMIDE 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 TERIMIDE.**
  - **talk to your doctor if you plan to become pregnant or before you stop taking this medicine.**
- **If you are male:**
  - **talk to your doctor about birth control that you and your female partner should use during treatment. You and your female partner should use reliable methods of birth control while you are taking TERIMIDE. TERIMIDE remains in your blood after you stop taking it, so continue using**

- reliable birth control until TERIMIDE blood levels have been checked and are low enough.**
- **tell your doctor if your female partner plans to become pregnant.**
  - **Tell your doctor if you need to have a vaccination during treatment with this medicine or for 6 months after stopping treatment.**
  - **Tell your doctor immediately if you:**
    - have an infection or notice chills or a fever or signs of an infection while taking this medicine
    - 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
  - If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking TERIMIDE.
  - Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
  - **If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**  
It may affect other medicines used during surgery.
  - **Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

## **Things you should not do**

- Do not take TERIMIDE 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.

## **Driving or using machines**

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

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

The effects of alcohol could be made worse while taking TERIMIDE. It is recommended you minimise your alcohol intake while taking this medicine.

## **Looking after your medicine**

- Keep your tablets in a cool dry place where the temperature stays below 25°C.
- Keep your tablets in the pack until it is time to take them.

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

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.**

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 take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

## **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.

If you are over 65 years of age you may have an increased chance of getting side effects.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>● diarrhoea</li><li>● rashes, itchy skin</li><li>● hair loss</li><li>● weight loss</li><li>● unusual tiredness or weakness</li><li>● numbness or tingling of hands or feet</li><li>● thickened, inflamed, red patches on the skin, which may be accompanied with whitish scaly skin, or accompanied by white pus-filled bumps</li><li>● painful rash or blisters on the skin</li><li>● oral blisters and lesions</li><li>● nail disorders</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>● signs and symptoms of severe infection, such as fever</li><li>● severe upper stomach pain, often with nausea and vomiting</li><li>● severe skin rash or sores in your mouth</li><li>● pale skin, fatigue, or proneness to bruising</li><li>● if you develop new or worsening symptoms such as cough or trouble breathing, with or without a fever</li><li>● 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</li></ul>	<p><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● inflammation of the colon, symptoms include diarrhoea usually with blood and mucus</li> <li>● light sensitivity, headache, stiff neck, seizures, unconsciousness, and disorientation</li> </ul> <p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>● swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing</li> <li>● hives</li> <li>● fainting</li> <li>● yellowing of the skin and eyes (jaundice)</li> <li>● thickened patches of red skin</li> </ul>	

**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](http://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 TERIMIDE contains

<b>Active ingredient (main ingredient)</b>	Teriflunomide 14 mg
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● colloidal anhydrous silica</li><li>● hyprolose</li><li>● lactose monohydrate</li><li>● magnesium stearate</li><li>● maize starch</li></ul>

	<ul style="list-style-type: none"> <li>• microcrystalline cellulose</li> <li>• OPADRY complete film coating system 03F505071 BLUE (ID 114102)</li> <li>• purified water</li> <li>• sodium starch glycollate type A</li> </ul>
<b>Potential allergens</b>	Lactose

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

## **What TERIMIDE looks like**

TERIMIDE tablets are pale blue to pastel blue, pentagonal film-coated tablets debossed with "L" on one side and "598" on the other side. TERIMIDE tablets are available in blister packs of 28 tablets. (AUST R 299149).

## **Who distributes TERIMIDE**

TERIMIDE is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatrix

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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