

Teriflunomide (ter" i floo' noe mide) Tablets, for oral use

Read this Medication Guide before you start using teriflunomide tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about teriflunomide tablets?

Teriflunomide tablets may cause serious side effects, including:

- **Liver problems:** Teriflunomide tablets may cause serious liver problems, including liver failure that can be life-threatening and may require liver transplant. Your risk of developing serious liver problems may be higher if you already have liver problems or take other medicines that also affect your liver. Your doctor should do blood tests to check your liver:

- o within 6 months before you start taking teriflunomide tablets
- o 1 time a month for 6 months after you start taking teriflunomide tablets

Call your doctor right away if you have any of the following symptoms of liver problems:

- o nausea
 - o vomiting
 - o stomach pain
 - o loss of appetite
 - o tiredness
 - o your skin or the whites of your eyes turn yellow
 - o dark urine
- **Harm to your unborn baby:** Teriflunomide tablets may cause harm to your unborn baby. Do not take teriflunomide tablets if you are pregnant. Do not take teriflunomide tablets unless you are using effective birth control.
 - o If you are a female, you should have a pregnancy test before you start taking teriflunomide tablets. Use effective birth control during your treatment with teriflunomide tablets.
 - o After stopping teriflunomide tablets, continue using effective birth control until you have blood tests to make sure your blood levels of teriflunomide tablets are low enough. If you become pregnant while taking teriflunomide tablets or within 2 years after you stop taking it, tell your doctor right away.
 - o **For men taking teriflunomide tablets:**
 - If your female partner plans to become pregnant, you should stop taking teriflunomide tablets and ask your doctor how to quickly lower the levels of teriflunomide tablets in your blood.
 - If your female partner does not plan to become pregnant, you and your female partner should use effective birth control during your treatment with teriflunomide tablets. Teriflunomide tablets remains in your blood after you stop taking it, so continue using effective birth control until teriflunomide tablets blood levels have been checked and they are low enough.

Teriflunomide tablets may stay in your blood for up to 2 years after you stop taking it. Your doctor can prescribe a medicine to help lower your blood levels of teriflunomide tablets more quickly. Talk to your doctor if you want more information about this.

What is teriflunomide tablet?

- Teriflunomide tablet is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- It is not known if teriflunomide tablets are safe and effective in children.

Who should not take teriflunomide tablets?

Do not take teriflunomide tablet if you:

- have severe liver problems.
- are pregnant or are of childbearing age and not using effective birth control.
- have had an allergic reaction to leflunomide, teriflunomide or any other ingredients in teriflunomide tablets. Please see the end of this Medication Guide for a complete list of ingredients in teriflunomide tablets.
- take a medicine called leflunomide.

What should I tell my doctor before taking teriflunomide tablets?

Before you take teriflunomide tablets, tell your doctor about all of your medical condition, including if you:

- have liver or kidney problems.
- have a fever or infection, or you are unable to fight infections.
- have numbness or tingling in your hands or feet that is different from your MS symptoms.
- have diabetes.
- have had serious skin problems when taking other medicines.
- have breathing problems.
- have high blood pressure.
- are breastfeeding or plan to breastfeed. It is not known if teriflunomide passes into your breast milk. You and your doctor should decide if you will take teriflunomide tablets or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using teriflunomide tablets and other medicines may affect each other causing serious side effects. Teriflunomide tablets may affect the way other medicines work, and other medicines may affect how teriflunomide tablets works.

Especially tell your doctor if you take medicines that could raise your chance of getting infections, including medicines used to treat cancer or to control your immune system.

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

How should I take teriflunomide tablets?

- Take teriflunomide tablets exactly as your doctor tells you to take it.
- Take teriflunomide tablets 1 time each day.
- Take teriflunomide tablets with or without food.

What are possible side effects of teriflunomide tablets?

Teriflunomide tablets may cause serious side effects, including:

- see **“What is the most important information I should know about teriflunomide tablets?”**
- **decreases in your white blood cell count.** Your white blood cell counts should be checked before you start taking teriflunomide tablets. When you have a low white blood cell count you:
 - o **may have more frequent infections.** You should have a skin test for TB (tuberculosis) before you start taking teriflunomide tablets. Tell your doctor if you have any of these symptoms of an infection:
 - fever
 - tiredness
 - body aches
 - chills
 - nausea
 - vomiting
 - o **should not receive certain vaccinations during your treatment** with teriflunomide tablets and for 6 months after your treatment with teriflunomide tablets ends.
- **allergic reactions.** Stop taking teriflunomide tablets and call your doctor right away or get emergency medical help if you have difficulty breathing, itching, swelling on any part of your body including in your lips, eyes, throat, or tongue.
- **serious skin reactions.** Teriflunomide tablets may cause serious skin reactions that may lead to death. Stop taking teriflunomide tablets and call your doctor right away or get emergency medical help if you have any of the following symptoms: rash or redness and peeling, mouth sores or blisters.
- **other types of allergic reactions or serious problems that may affect different parts of the body such as your liver, kidneys, heart, or blood cells.** You may or may not have a rash with these types of reactions. Other symptoms you may have are:
 - o severe muscle pain
 - o swollen lymph glands
 - o swelling of your face
 - o unusual bruising or bleeding
 - o weakness or tiredness
 - o yellowing of your skin or the white part of your eyes

If you have a fever or rash with any of the above symptoms, stop taking teriflunomide tablets and call your doctor right away.

- **numbness or tingling in your hands or feet that is different from your MS symptoms.** You have a higher chance of getting these symptoms if you:
 - o are over 60 years of age
 - o take certain medicines that affect your nervous system
 - o have diabetes

Tell your doctor if you have numbness or tingling in your hands or feet that is different from your MS.

- **high blood pressure.** Your doctor should check your blood pressure before you start taking teriflunomide tablets and while you are taking teriflunomide tablets.
- **new or worsening breathing problems.** These may be serious and lead to death. Call your doctor right away or get emergency medical help if you have shortness of breath or coughing with or without fever.

The most common side effects of teriflunomide tablets include:

- headache
- diarrhea
- nausea
- hair thinning or loss (alopecia)
- increases in the results of blood tests to check your liver function

These are not all the possible side effects of teriflunomide tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store teriflunomide tablets?

- Store teriflunomide tablets 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
- Keep teriflunomide tablets and all medicines out of the reach of children.
- Bottles of 30's count comes in a child-resistant package.

General information about the safe and effective use of teriflunomide tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use teriflunomide tablets for a condition for which it was not prescribed. Do not give teriflunomide tablets to other people, even if they have the same symptoms you have. It may harm them.

You can ask your doctor or pharmacist for information about teriflunomide tablets that is written for health professionals.

What are the ingredients in teriflunomide tablets?

Active ingredient: teriflunomide

Inactive ingredients in 7 mg and 14 mg tablets: lactose monohydrate, corn starch, sodium starch glycolate, hydroxypropyl cellulose, microcrystalline cellulose, colloidal silicon dioxide, and magnesium stearate. The film coating for the 14 mg tablet is made of hypromellose, titanium dioxide, talc, polyethylene glycol 8000, talc, and FD&C Blue#2 Aluminium Lake.

In addition, the 7 mg tablets also contain iron oxide yellow.

For more information, call Alembic Pharmaceuticals Limited at 1-866-210-9797.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Medication Guide available at <http://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

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