



TERIFLUNOMIDE F. C. TABLET

TERIFLUNOMIDE

TERIFLUNOMIDE F. C. TABLET FOR ORAL USE

Read this patient information carefully before you start taking Teriflunomide because it answers some common questions about Teriflunomide. This medication is prescribed for your current condition, therefore do not use it in similar cases and do not recommend it to others.

To report SUSPECTED ADVERSE REACTIONS, contact Noavaran Daroui Kimia Co. at +982166433514 or send email to medical@kimia-pharma.co

Read this patient information carefully before you start taking Teriflunomide because it contains important information for you. This leaflet does not take the place of talking with your healthcare provider about your medical condition or treatment.

Composition

Each film-coated tablet Teriflunomide 7 mg contains: 7 mg of Teriflunomide.
Each film-coated tablet Teriflunomide 14 mg contains: 14 mg of Teriflunomide.

Mechanism of action

Teriflunomide is an immunomodulatory agent with anti-inflammatory properties.

Pharmacokinetic

Absorption

Median time to reach maximum plasma concentrations is between 1 to 4 hours.

Distribution

The plasma protein binding of Teriflunomide is >99%.

Metabolism

Teriflunomide is the major circulating moiety detected in plasma.

Elimination

Teriflunomide is eliminated mainly through direct biliary excretion of unchanged drug as well as renal excretion of metabolites. The total body clearance of Teriflunomide is 30.5 mL/h.

Indication

Teriflunomide is indicated for the treatment of 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 is safe and effective in children.

Dosage and Administration

The recommended dose of Teriflunomide is 7 mg or 14 mg orally once daily. Teriflunomide can be taken with or without food.

Side effects / Adverse reactions

It should be noted that these side effects do not occur in all patients. These are not all the possible side effects of Teriflunomide. For more information, ask your healthcare provider or pharmacist.

Teriflunomide may cause serious side effects including:

- **decreases in your white blood cell count.** Your white blood cell counts should be checked before you start taking Teriflunomide. 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. Tell your doctor if you have any of these symptoms of an infection:
 - fever
 - chills
 - tiredness
 - nausea
 - body aches
 - vomiting
 - o **should not receive certain vaccinations during your treatment** with Teriflunomide and for 6 months after your treatment with Teriflunomide ends.
- **allergic reactions.** Stop taking Teriflunomide 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 may cause serious skin reactions that may be life threatening. Stop taking Teriflunomide 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 and call your doctor right away.

- **numbness or tingling in your hands or feet that is different from you MS symptoms.** You have a greater chance of getting peripheral neuropathy 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.

- **new or worsening breathing problems.** These may be serious and may be life threatening. Call your doctor right away or get emergency medical help if you have shortness of breath or coughing with or without fever.
- **high blood pressure.** Your doctor should check your blood pressure before you start taking Teriflunomide and while you are taking Teriflunomide.
- **liver problems:** Teriflunomide may cause serious liver problems, including liver failure that can be life-threatening and may require a 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
 - o 1 time a month for 6 months after you start taking Teriflunomide

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

Teriflunomide is contraindicated in patients with severe hepatic impairment.

Call your healthcare provider right away if you have aforementioned symptoms.

The most common side effects

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

Tell your doctor if you have any side effect that bothers you or that does not go away.

Drug interactions

- Coadministration of Teriflunomide with warfarin requires close monitoring of the international normalized ratio (INR).
- Teriflunomide may increase the systemic exposures of ethinylestradiol and levonorgestrel. Consideration should be given to the type or dose of contraceptives used in combination with Teriflunomide.
- In patients taking Teriflunomide, exposure of paclitaxel, pioglitazone, repaglinide, rosiglitazone, cefaclor, cimetidine, ciprofloxacin, penicillin G, ketoprofen, furosemide, methotrexate, zidovudine may be increased. Monitor these patients and adjust the dose of the concomitant drug(s) as required.
- In patients taking Teriflunomide, exposure of alosetron, duloxetine, theophylline and tizanidine may be reduced. Monitor these patients and adjust the dose of the concomitant drug(s) as required.
- For a patient taking Teriflunomide, the dose of rosuvastatin should not exceed 10 mg once daily. For mitoxantrone, methotrexate, rifampin, atorvastatin, nateglinide, pravastatin, repaglinide, and simvastatin, consider reducing the dose of these drugs and monitor patients closely for signs and symptoms of increased exposures to the drugs while patients are taking Teriflunomide.
- Rifampicin, carbamazepine, phenobarbital, phenytoin and St John's Wort should be used with caution during the treatment with Teriflunomide.

Warnings

Before you take Teriflunomide, tell your doctor about all of your medical conditions, 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.

Do not use alcoholic products during treatment with Teriflunomide.

Do not take Teriflunomide 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.
- take a medicine called leflunomide.

Since Teriflunomide tablets contain lactose, patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption, should not take this medicinal product.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

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.

Missed dose

If you miss a dose, do not take a double dose to make up for a forgotten tablet. Take your next dose at the scheduled time.

Overdose

If you take too much Teriflunomide, call your doctor or go to the nearest hospital emergency room right away. In the event of clinically significant overdose or toxicity, cholestyramine or activated charcoal is recommended to accelerate elimination.

Pregnancy and lactation

- Teriflunomide may cause harm to your unborn baby. **Do not take Teriflunomide if you are pregnant.**
- If you are a female, you should have a pregnancy test before you start taking Teriflunomide. Use effective birth control during your treatment with Teriflunomide.
- After stopping Teriflunomide, continue using effective birth control until you have blood tests to make sure your blood levels of Teriflunomide are low enough. If you become pregnant while taking Teriflunomide or within 2 years after you stop taking it, tell your doctor right away.
- o **For men taking Teriflunomide:**
- If your female partner plans to become pregnant, you should stop taking Teriflunomide and ask your doctor how to quickly lower the levels of Teriflunomide 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. Teriflunomide remains in your blood after you stop taking it, so continue using effective birth control until Teriflunomide blood levels have been checked and they are low enough.

It is not known if Teriflunomide passes into your breast milk. Because of the potential for adverse reactions in a breastfed infant from Teriflunomide, **you should not breastfeed during treatment with Teriflunomide.** You and your doctor should decide if you will take Teriflunomide or breastfeed.

Patient information

- Take Teriflunomide 1 time each day.
- Take Teriflunomide with or without food.
- Teriflunomide 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 more quickly. Talk to your doctor if you want more information about this.

Storage

- Keep away from light and moisture. Store below 30°C.
- Keep out of the reach of children.
- Keep in the original container.
- Keep the desiccant in the bottle. Do not swallow the desiccant pack found in the bottle.
- Safely throw away medicine that is out of date or that you no longer need.

Packaging

Bottle of 28 F. C. Tablets.

MANUFACTURED BY:

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www.kimia-pharma.co

References

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/202992s013s015lbl.pdf

BNF 81: March - September 2021

https://www.ema.europa.eu/en/documents/product-information/aubagio-epar-product-information_en.pdf