

Important Safety Information

Patient Card

Teriflunomide BOS (Teriflunomide) 14 mg and 7 mg film-coated tablets

This patient card provides important information on the risks of teriflunomide BOS (teriflunomide). Keep it in a safe place and show it to any doctor or healthcare professional who is treating you (e.g. in case of an emergency). You should also read the patient information leaflet for further information.

Please fill the below section or ask your doctor to do it

Name	
Date of Birth	
Date of teriflunomide first prescribed	
Hospital	
Prescriber's name	
Prescriber's phone number	

Important side effects

Teriflunomide reduces the activity of the immune system (immunomodulator). In some people, teriflunomide can cause liver damage (hepatitis) and it may also reduce the production of white blood cells that fight infection (neutrophils) and platelets that are involved in blood clotting.

Your liver function tests, and blood pressure should be checked regularly during teriflunomide treatment, and your full blood count should be checked if necessary. These tests should also be checked before starting treatment.

If you have any of the following side effects, please contact your doctor immediately:

- Yellow skin or yellowing of the whites of your eyes (jaundice), unexplained nausea or vomiting, abdominal pain, or darker urine than normal. These are the symptoms of a liver problem.
- Signs of an infection including, pain on passing urine, confusion, high temperature (fever), cough.

For female patients of childbearing potential including girls and their parents/caregivers

- Teriflunomide should not be used in pregnancy or in women of childbearing potential if they are not using effective contraceptives because it can cause serious birth defects.
- Do not start teriflunomide when you are pregnant, or you think you may be pregnant. Your doctor may ask you to do a pregnancy test to make sure.
- Effective contraception should be used during and after teriflunomide treatment until the blood levels are low. Your doctor will provide counselling on the potential risks to an unborn baby and on the need for effective contraception.

- Tell your doctor if you want to change your method of contraception or plan to become pregnant after stopping treatment with Teriflunomide BOS. You should also discuss with your doctor if you plan to or are breastfeeding.
- If you suspect that you are pregnant while taking Teriflunomide BOS or in the two years after you have stopped treatment, you must contact your doctor immediately for a pregnancy test. If the test confirms that you are pregnant, your doctor may suggest treatment with certain medicines to speed up the removal of teriflunomide from your body, as this may decrease the risk to your baby.
- The parents or caregivers of girls should contact their daughter's doctor when they have their first period so that she can be counselled on the risk of birth defects during pregnancy and given advice on appropriate contraception.

Reporting of side effects

If you experience any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects, even if it was not listed in the package leaflet.

You can report side effects directly by contacting:

Munirah Ibrahim AlSaqabi | Boston Oncology Arabia Limited
King Abdelaziz Street, 11562, Riyadh, Saudi Arabia
Phone: 9200 33871 | Mobile: +966 5352 48819
E-mail: pv@bostononcology.com

The National Pharmacovigilance Centre (NPC)
SFDA Call Centre: 19999 | E-mail: npc.drug@sfd.gov.sa
Website: <https://ade.sfd.gov.sa/>

By reporting side effects, you can help provide more information on the safety of this medicine.

References:

- 1 Teriflunomide BOS Leaflet
2. Teriflunomide healthcare professional education/discussion guide Medicines.org.uk. [cited 20 October 2021]. Available from: <https://www.medicines.org.uk/emc/rmm/292/Document>