

Teriflunomide BOS

English Patient Card

This patient card provides important information on the risks of Teriflunomide BOS. Please show this card to any doctor or healthcare professional involved in your medical care (e.g. in case of an emergency).

You should also read the patient information leaflet for further information.

Please fill in the section below, or ask your doctor to do so

Name

Date of Birth

Indication

Dosage

Prescriber Name

Prescriber Phone

Important Side Effects

Teriflunomide BOS reduces the activity of the immune system (immunomodulator). In some people, Teriflunomide BOS can cause liver damage (hepatitis) and 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 BOS 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, or swollen glands

For Women of Childbearing Potential, Including Girls and their Parents/Caregivers

- Teriflunomide BOS 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 BOS 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 BOS 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 are breastfeeding, or plan to.

- 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 BOS 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 they can be counselled on the risk of birth defects during pregnancy and given advice on appropriate contraception.

You can report any side effects to SFDA via:

The National Pharmacovigilance Centre (NPC)

SFDA Call Center: 19999 | E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa/>

Or to the pharmacovigilance department of Boston Oncology Arabia Limited via:

Boston Oncology Arabia Limited

Airport Road, 13413, Riyadh, Saudi Arabia

Phone: +966 547 643 672

E-mail: pv@bostononcology.com

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

For full information on all possible side effects please see the Teriflunomide BOS's Patient Information Leaflet.