

For further information, please contact medical information safety@amaroxpharma.com
Version 02 Date of Preparation: March 2025.
Date of MHRA approval: March 2025.

Emergency phone
number for neurologist:

Name of neurologist:

Hospital:

Date teriflunomide first prescribed:

Patient's name:

PATIENT CARD: UK

This patient card provides important information on the risks of Teriflunomide. 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 report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the *Apple App Store* or *Google Play Store*
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine. Suspected adverse reactions should also be reported to AmaroX: Tel: 020-39720005.
Email: safety@amaroxpharma.com



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, swollen glands.

For women of childbearing potential including girls and their parents/caregivers

- Teriflunomide should not be used in pregnancy or in women of child-bearing potential if they are not using effective contraception 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. You should also discuss with your doctor if you plan to or are breastfeeding.
- If you suspect that you are pregnant while taking teriflunomide 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 carers 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.

Date of MHRA approval: March 2025.