Teriflunomide Dr. Reddys 14 mg film-coated tablets
teriflunomide

Patient's name: _____

Date teriflunomide first prescribed: _____

Name of neurologist: _____

number for neurologist: _____

Emergency phone _____

PATIENT CARD: MALTA

This patient card provides important information on the risks of Dr.Reddy's (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.

Suspected adverse reactions that may occur during treatment should be reported via adverse drug reactions (ADRs) to Malta Medicine Authority via the ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal.

For further information regarding this medication please contact local representative: EJ Busuttil Ltd.
Phone: 21447184 (service is available 24/7)
Email: safety@ejbusuttil.com
Office Adress:
Busuttil Buildings, Triq l-Ghadam,
Central Business District Zone 1,
Birkirkara CBD1060 MALTA

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 Dr.Reddy's: Tel: 01748 828 873.
Email: drreddysgb@eu.propharmagroup.com

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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.
- Women are encouraged to report any exposure during pregnancy, along with any suspected adverse reactions, to Dr. Reddy's by calling: Tel: 01748 828 873 or visiting Spanish

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Pharmacovigilance System for Medicinal Products for Human Use: https://www.notificaram.es
irrespective of adverse outcome

Approved by Malta Medicines Authority on 05/05/2025.