

PATIENT CARD

AXYLA® (Teriflunomide) 14 mg film-coated tablets

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

Patient's name:

Date teriflunomide first prescribed:

Hospital:

Name of neurologist:

Emergency phone number for neurologist:

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 fever, shivering, pain on passing urine or confusion.

For female patients of childbearing potential

- 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.
- Use effective contraception while taking teriflunomide. Tell your doctor if you want to change your method of contraception or plan to become pregnant after stopping treatment with Axyla®. You should also discuss with your doctor if you plan to or are breastfeeding.
- If you suspect that you are pregnant while taking Axyla® 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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects. You can report side effects directly by **contacting**:

Local representative at MS Pharma Saudi

Address: King Abdulaziz road - Alrabea District - Grand Center 1st floor – Front of Kingdom Hospital
P.O Box 54850 Riyadh, 11524 Saudi Arabia

- Phone: + 966112790122 Ext. 6013
- Fax: +966112471323
- Mobile: + 966548933555

The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA)

- SFDA call center: 19999
- Toll free phone: 8002490000
- Fax: +966-11-2057662
- E-mail: npc.drug@sfda.gov.sa
- Website: <http://ade.sfda.gov.sa/>

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

References

- [1] Axyla® Leaflet
- [2] Teriflunomide patient card Medicines.org.uk. [cited 25 February 2021]. Available from: <https://www.medicines.org.uk/emc/rmm/293/Document>