PV-RMM-AXY-PRC-KSA-11.23-2.0

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

PATIENT CARD:

Axyla® (Teriflunomide) 14 mg film-coated tablets

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

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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 infection include pain in passing urine, confusion, high temperature (fever), cough, and swollen glands.

For women 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 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 counseling 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 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.

- The parents or caregivers of female children should contact the prescribing physician once the female child is under Teriflunomide treatment and experiences menses for the first time. Counseling should be provided about contraception and the potential risk to the fetus.

Reporting of side effects

Report suspected adverse drug reactions associated with Axyla® (Teriflunomide) by contacting:

- **Pharmacovigilance department at MS Pharma:**
  - Email: pharmacovigilance@mspharma.com
  - Website: www.mspharma.com
  - Phone No: + 966112790122 Ext. 6013
  - Mobile: +0966548933555

- **The National Pharmacovigilance Center (NPC): (Saudi food and drug authority)**
  - Email: npc.drug@sfda.gov.sa
  - Website: https://ade.sfda.gov.sa/
  - Call Center: 19999