HEALTHCARE PROFESSIONAL EDUCATION/ DISCUSSION GUIDE:

AXYLA® (Teriflunomide) 14 mg film-coated tablets

MS pharma

HEALTHCARE PROFESSIONAL EDUCATION/DISCUSSION GUIDE:

AXYLA® (Teriflunomide) 14 mg film-coated tablets

Patient's name:	Patient's age:
Date of first visit:	Patient's gender: Male ☐ Female ☐
Date of first prescribed:	Today's date:

DISCUSS

- **Discuss the information below pertaining to the following risks with the patients**
- **Please read the SPC for full prescribing information**

Risk of haematological effects	Risk of liver effects
• Check full blood count before treatment initiation and as necessary based on clinical signs and symptoms during treatment	• Check liver function before treatment initiation and periodically during treatment • Patients should be counselled on the symptoms and signs of liver effects and told to contact their doctor immediately if any develop

Risk of hypertension	Risk of serious infections
• Check blood pressure before treatment initiation and periodically during treatment • Blood pressure elevation should be appropriately managed before and during treatment	• Patients should be told to contact their doctor immediately if they have any symptoms or signs of an infection • Patients should also inform their doctor if they are prescribed or taking any other medicines that affect the immune system

Risk of teratogenicity

- Pregnancy should be excluded in women of child-bearing potential before starting teriflunomide. Women of childbearing potential should use effective contraception during treatment and after treatment as long as teriflunomide plasma concentrations exceed 0.02 mg/l. During this period women should discuss any plans to conceive, stop or change contraception with their physician. Women should be advised to contact their physician as soon as possible if they might be pregnant for pregnancy testing, counselling, teriflunomide discontinuation and consideration of accelerated elimination

COUNSEL & HAND-OVER

Patient Card:

- Provide the patient with the patient card and discuss the content regularly during each consultation and at **least annually during treatment**
- Complete your contact details on the patient card and replace it as necessary
- Educate the patient to show this card to any doctor or heathcare professional involved in medical care (e.g. In case of an emergency)
- Advise the patient to contact their prescriber or general practitioner if they develop any signs or symptoms of the risks discussed in the patient card
- Discuss during each consultation the continued need for effective contraception during treatment
- Ensure adequate monitoring of patients when new prescriptions are issued including adverse reaction checks, and risk assessments and prevention

The patient has been informed about and understand the above mentioned risks and benefits associated with this treatment

Prescriber's name: ..... **Prescriber's signature:** .....

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 healthcare professional education/discussion guide Medicines.org.uk. [cited 25 February 2021]. Available from: https://www.medicines.org.uk/emc/rmm/292/Document

MS pharma