Important Risk Minimization Information for Healthcare Professionals

HEALTHCARE PROFESSIONAL EDUCATION/ DISCUSSION GUIDE.

Aubomide (Teriflunomide Tablets 14mg)

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

Please read the below SPC QR Barcode for full prescribing information

Version no: 2, November 2024

HEALTHCARE PROFESSIONAL EDUCATION/ DISCUSSION GUIDE:

Aubomide (Teriflunomide Tablets 14mg)

Patient's Name:	**Patients Age:**
Date of First Visit:	**Patient's gender:** ☐Male ☐Female
Date of first prescribed:	**Today's date:**

DISCUSS THE INFORMATION BELOW PERTAINING TO THE FOLLOWING RISKS WITH THE PATIENTS.

The objective of this document is:

- A healthcare professional educational or discussion guide is one of the educational materials which is crucial to ensure the safe and effective use of the product and appropriate management of the important selected risks.
- It is advised to be read carefully before prescribing or dispensing or administering the product.

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Associated Risks

Risk of liver effects:

- ☐ Check liver function before treatment initiation and periodically during treatment.
- ☐ Patients should be counselled on the signs and symptoms of liver effects (dark urine, nausea or vomiting and abdominal pain etc.) and told to contact their doctor immediately if any develop.

Risk of serious infections:

- ☐ Patients should be told to contact their doctor immediately if they have any signs or symptoms of an infection.
- ☐ Patients should also inform their doctor if they are prescribed or taking any other medicines that affect the immune system.
- ☐ Consider an accelerated elimination procedure in case of a serious infection.

Risk of hypertension

- ☐ Check blood pressure before treatment initiation and periodically during treatment
- ☐ Blood pressure elevation should be appropriately managed before and during treatment.

Risk of haematological effects

- ☐ Risk of decreased blood cells (affecting mainly white blood cells)
- ☐ Full blood count before treatment initiation and thereafter, if necessary, based on clinical signs or symptoms during treatment

Risk of teratogenicity

- ☐ Inform women of childbearing potential (WOCBP) that teriflunomide can cause serious birth defects so it is contraindicated in pregnancy, and they must use effective contraception during and after treatment until their teriflunomide blood levels are low. Women should contact their doctor immediately if they plan to conceive, stop, or change contraception during this time.
- ☐ Check the potential for pregnancy in all female patients before and during treatment.
- ☐ Tell the parents/caregivers of girls that they should contact their doctor for counselling on the risk of teratogenicity and contraceptive advice when she starts to menstruate
- ☐ Women should contact their physician immediately and stop teriflunomide if they become pregnant. Physicians will: discuss and consider the accelerated elimination procedure.

COUNSEL AND HANDOVER

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 healthcare 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 understands 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 from patients, all Healthcare professionals are required to strictly report it by contacting on following:

Saudi Food and Drug Authority (SFDA)	Pharmacovigilance Department (PPI)
SFDA call center: 19999 **E-mail: npc.drug@sfda.gov.sa** **Website: http://ade.sfda.gov.sa/** **Please visit the below barcode to report**	**E-mail: Abdulrahman@pharma.com.sa** **Mobile: +966 580303838** **Website: https://pharma.com.sa/** **Please visit the below barcode to report**

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