HEALTHCARE PROFESSIONAL EDUCATION/ DISCUSSION GUIDE:

Risks associated with the use of the product,

Bauda® (Teriflunomide) 14 mg

film-coated tablets

It is advised to read carefully before prescribing/dispensing/administering the product.

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

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

DISCUSS

This guideline is intended to inform healthcare professionals about the risks and important risk minimization information associated with the use of the product, it is advised to read carefully before prescribing/dispensing/administering the product.

• 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 **Monitoring:** **Before treatment:** • Blood pressure • Alanine aminotransferase/serum glutamic pyruvic transaminase (ALT/SGPT) • Complete blood cell count including differential white blood cell and platelet count.

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	During treatment: • Blood pressure • o Check periodically • Alanine aminotransferase/serum glutamic pyruvic transaminase (ALT/SGPT) • o Liver enzymes should be assessed every two weeks during the first 6 months of treatment, and at least every 8 weeks thereafter for at least 2 years from initiation of treatment. • • Complete blood cell counts should be performed based on clinical signs and symptoms (e.g.infections) during treatment.

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

Pregnant women, or women of childbearing potential who are not using reliable contraception during treatment with teriflunomide and thereafter as long as its plasma levels are above 0.02 mg/l. Pregnancy must be excluded before start of treatment (Refer to SPC).

Accelerated elimination procedure

After stopping treatment with teriflunomide:

• cholestyramine 8 g is administered 3 times daily for a period of 11 days, or cholestyramine 4 g three times a day can be used, if cholestyramine 8 g three times a day is not well tolerated, alternatively, 50 g of activated powdered charcoal is administered every 12 hours for a period of 11 days.

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 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 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 ALPHA Pharma Saudi

Address: Alpha Pharma Industry ,Office.10.1st floor.Khurais Commercial Complex Makkah Br.Rd.As Sulimaniyah,Riyadh 12621

- Telephone:+966 11 293 1773 Ext: 111
- Fax: +966112471323
- Mobile:+966 53 040 8553
- Email: pv@alphapharma.com.sa

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

- SFDA call center: 19999
- 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. Bauda®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