Teriflunomide BOS

Healthcare Professional Education/Discussion Guide

This educational material is essential to ensure the safe and effective use of the product and appropriate management of the important risks.

We advise you to read this document carefully before prescribing/dispensing/administering Teriflunomide.

You can report any side effects to SFDA via:

The National Pharmacovigilance Centre (NPC)
SFDA Call Center: 19999 | E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/

Or to the pharmacovigilance department of Boston Oncology Arabia Limited via:

Boston Oncology Arabia Limited
Airport Road, 13413, Riyadh, Saudi Arabia
Phone: +966 547 643 672
E-mail: pv@bostononcology.com

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

For full information on all possible side effects please see the Teriflunomide BOS Patient Information Leaflet.

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Patient's Name:	Patient's Age:
Date of First Visit:	Patient's Gender: ☐ Male ☐ Female
Date First Prescribed:	Today's Date:

Discuss

Discuss the following risks with the patient/parent/caregiver, explain the monitoring requirements and tell them what they should do if patients experience specific signs or symptoms.

Please read the SPC for full prescribing information.

Risk of Hematological 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 Hypertension

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

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 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 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 & 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
- Counsel and inform WOCBP, including adolescents and their parents/caregivers, before treatment and regularly thereafter about potential risk for the fetus
- 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: _____

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