a SUN PHARMA company

Teriflunomide Taro (teriflunomide) 14 mg tablets, once-daily.

HEALTHCARE PROFESSIONAL EDUCATION/DISCUSSION GUIDE

This brochure was revised in December 2024.

- Discuss with the patient the risks addressed in this brochure
- Please read the summary of the product characteristics (SPC) for full prescribing information

Patient's name: _____ Patient's age: _____

First visit date: _____ patient's gender: ☐ Male ☐ Female

First prescription date: _____ Today's date: _____

Discuss

Complete Blood Count (CBC)

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

Infections/Serious Infections

- ◇ Risk of (serious opportunistic) infections
- ◇ Need to contact their doctor in case signs or symptoms of infection develop or if the patients take other medicines that affect the immune system
- ◇ Consider an accelerated elimination procedure in case of a serious infection

Blood Pressure

- ◇ Risk of hypertension
- ◇ Check blood pressure before treatment initiation and periodically during treatment
- ◇ Need to contact their doctor in case they develop hypertension

Hepatic Effects

- ◇ Risk of liver effects
- ◇ Check liver function before treatment initiation and periodically during treatment
- ◇ Signs and symptoms of liver disease
- ◇ Need to contact their doctor immediately in case symptoms develop

For women of childbearing potential (WOCP) including adolescents

- ◇ Potential risk of teratogenicity
- ◇ Check pregnancy status before starting treatment
- ◇ Check potential for pregnancy in all WOCP including patients below 18 years old
- ◇ Pregnancy should be excluded
- ◇ Need for effective contraception before starting, during and after treatment
- ◇ Need to contact their doctor immediately if they stop contraception, or prior to changing contraceptive
- ◇ Need to stop Teriflunomide Taro and contact their doctor immediately in case of pregnancy
- ◇ Consider accelerated elimination procedure
- ◇ **Report any pregnancy case to Taro by calling 1-800-46-46-64, irrespective of adverse outcomes observed**
- ◇ Contact Taro for information regarding the measurement of teriflunomide plasma concentration.

Parents/caregivers of female child

- ◇ Need for parents/caregivers to contact the doctor once the female child experience menses

Hand-Over

- Complete the contact details in the patient card and replace it when necessary
- Provide the patient/legal representative with the patient card and discuss the content regularly during each consultation **at least annually during treatment**
- Educate the patient/legal representative to show this card to any doctor or healthcare professional involved in medical care (e.g. In case of an emergency)
- Remind the patient to contact their doctor in case of any adverse events especially in case of symptoms of liver disorders and infection discussed in the Patient Card
- Counsel and inform before treatment and regularly thereafter women of childbearing potential (WOCP) including adolescents/their parents/caregivers about potential risk for the foetus
- Remind the patient to contact their doctor in case of pregnancy.

Reporting suspected adverse reactions after authorisation of teriflunomide is important; it allows continued monitoring of the benefit/risk balance of teriflunomide

Healthcare professionals are asked to report adverse reactions to the Ministry of Health at: https://sideeffects.health.gov.il

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

Prescriber's name: _____ **prescriber's signature:** _____