

Teriflunomide Teva®

HEALTHCARE PROFESSIONAL GUIDE

- Discuss with the patient the risks addressed in this brochure
- Please read the summary of 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: _____

TRF-HCP-03

HAND-OVER

Patient Card:

- 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 authorization of teriflunomide is important; it allows continued monitoring of the benefit/ risk balance of teriflunomide

- Healthcare professionals are asked to report any suspected 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: _____

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 immediately 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 Teva and to contact doctor immediately in case of pregnancy
- ❑ Consider accelerated elimination procedure
- ❑ **Report any pregnancy case to Teva by calling 1-800-805-005, irrespective of adverse outcomes observed**
- ❑ Contact Teva 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