

## 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 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 understand the above mentioned risks and benefits associated with this treatment**

Prescriber's name: \_\_\_\_\_

Prescriber's signature: \_\_\_\_\_

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This guide was approved according to the guidelines of the Ministry of Health on 02/07/2024

MAT-IL-2400529

Once-daily  
**AUBAGIO**<sup>®</sup>  
(teriflunomide) 14 mg tablets

## 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: <input type="checkbox"/> Male <input type="checkbox"/> Female |
| First prescription date: | Today's date:   |

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# 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 patient takes 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 AUBAGIO and to contact doctor immediately in case of pregnancy
- Consider accelerated elimination procedure
- **Report any pregnancy case to Sanofi by calling 098633081, irrespective of adverse outcomes observed**
- Contact Sanofi 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 experiences menses