Once-daily AUBAGIO® (teriflunomide)

# HEALTHCARE PROFESSIONAL GUIDE: IRELAND

DISCUSS

- **Discuss with the patient the risks addressed in this brochure**
- **Please read the SPC for full prescribing information**

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

## Complete Blood Count (CBC)

Discuss with patients the:

- ☐ Risk of decreased blood cell counts (affecting mainly white blood cells)
- ☐ The need for complete blood counts (CBCs) before treatment initiation and periodically during treatment

## Blood pressure

- ☐ Check blood pressure before treatment initiation and periodically during treatment
- ☐ Check if patient has a history of hypertension and blood pressure should be appropriately managed during treatment
- ☐ Educate patients about the need to contact their doctor in case they develop hypertension

## Hepatic Effects

Educate patients about:

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

## Infections/Serious Infections

Discuss with patients the:

- ☐ Need to contact their doctor in case signs or symptoms of infections develop or if the patient takes other medicines that affect the immune system
- ☐ If serious infection occurs, consider the accelerated elimination procedure

## For women of childbearing potential (WOCBP) including adolescents

- ☐ Pregnancy should be excluded
- ☐ Signs and symptoms of liver disease
- ☐ Check pregnancy status before starting treatment
  - in all female patients, including WOCBP <18 years old

Educate female patients of child-bearing potential on the:

- ☐ Need to contact their doctor immediately if they stop contraception, or prior to changing contraceptive
- ☐ If serious infection occurs, consider the accelerated elimination procedure
- ☐ Need to stop teriflunomide and to contact their doctor immediately in case of pregnancy

## For women of childbearing potential (WOCBP) including adolescents (continued)

If a female patient becomes pregnant:

- ☐ Treatment with teriflunomide should be discontinued
- ☐ Consider and discuss with the patient the accelerated elimination procedure
- ☐ Report any pregnancy case to Sanofi by emailing IEpharmacovigilance@sanofi.com or calling 01 403 5600, irrespective of adverse outcomes observed
- ☐ Contact Sanofi Medical Information by emailing IEmedinfo@sanofi.com or calling 01 403 5600 for information regarding the measurement of teriflunomide plasma concentration

## Female children and/or their parents/caregivers

- ☐ Advise female children and/or their parents/caregivers to contact the doctor once the female child experiences menses

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# HEALTHCARE PROFESSIONAL EDUCATION/DISCUSSION GUIDE: IRELAND

HANDOVER

**Patient Card:**

- Provide the patient and/or their parent/caregiver with a patient card, including filling in their contact details, and replace it when necessary
- Discuss the content regularly during each consultation and at least annually during treatment. Provide replacement cards as necessary
- Educate the patient and/or their parent/caregiver 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 MS doctor and/or General Practitioner if they experience any of the signs and symptoms discussed in the patient education card, including liver problems and infections

**Additional HCP Instructions:**

- At prescription renewal, adverse events are checked, ongoing risks and their prevention are discussed, and checks are made to ensure adequate monitoring is taking place
- Always read this guide in conjunction with the approved SmPC which can be found on www.medicines.ie
- Counsel and inform before treatment, and regularly thereafter WOCBP including adolescents/their parents/caregivers about the potential risk for the foetus
- Remind the patient to contact their doctor in case of pregnancy

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

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie. Side effects should also be reported to Sanofi: Tel: 01 403 5600 e-mail: IEPharmacovigilance@sanofi.com

**Prescriber's name:** **Prescriber's signature:**