Once-daily AUBAGIO® (teriflunomide)

HEALTHCARE PROFESSIONAL EDUCATION/DISCUSSION 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

Risk of liver 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

Risk of (serious opportunistic) 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
- ☐ Check pregnancy status before starting treatment
  - in all female patients, including WOCBP <18 years old

Educate female patients of child-bearing potential on the:

- ☐ Potential risk of teratogenicity and the need for effective contraception before starting and during treatment
- ☐ Need to contact their doctor immediately if they stop contraception, or prior to changing contraceptive
- ☐ Need to stop teriflunomide and to contact their doctor immediately in case of pregnancy

If a female patient becomes pregnant:

- ☐ Treatment with teriflunomide should be discontinued
- ☐ Consider and discuss with the patient the accelerated elimination procedure
- ☐ Encourage enrolment in pregnancy registry
- ☐ National coordination centre which manages patient enrolment in the registry: St Vincent's Hospital, Dublin (01 2214209)
- ☐ More information on the importance of contraception is available on the MS One to One website

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

SANOFI GENZYME

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HAND-OVER

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

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: _____