



- **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:	

DISCUSS



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 LEpharmacovigilance@sanofi.com or calling 01 403 5600, irrespective of adverse outcomes observed
- ☐ Contact Sanofi Medical Information by emailing LEmedinfo@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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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:
