

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

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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Once-daily
AUBAGIO[®]
(teriflunomide) ^{14 mg} tablets

AUBAGIO is available in 14 mg and 7 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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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 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 yrs 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 Srl***
PharmacovigilanceMalta@sanofi.com
Contact *Sanofi Srl* for information regarding the measurement of terifunomide plasma concentration.
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- Availability of MS One to One website for information on effective contraception

Parents/caregivers of female child

- Need for parents/caregivers to contact the doctor once the female child experience menses

Call for Reporting

Healthcare professionals are encouraged to report all ADRs to the Medicines Authority at

postlicensing.medicinesauthority@gov.mt

Report Form can be downloaded from

<http://www.medicinesauthority.gov.mt/adrportal>

Alternatively any ADRs can be reported to Sanofi Srl
PharmacovigilanceMalta@sanofi.com