

# 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 WOCP including adolescents/their parents/caregivers about potential risk for the foetus.

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

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

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

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

AUBAGIO is available in 14 mg and 7 mg tablets.

## HEALTHCARE PROFESSIONAL EDUCATION/DISCUSSION GUIDE



- Discuss with the patient the risks addressed in this brochure
- Please read the 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:

# 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



- ❑ Risk of (serious opportunistic) infections
- ❑ Need to contact their doctor immediately in case signs or symptoms of infection develop or if the patients take 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



- ❑ 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

## Parents/caregivers of child female

- ❑ 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](mailto: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 at [PharmacovigilanceMalta@sanofi.com](mailto:PharmacovigilanceMalta@sanofi.com)