

HEALTHCARE PROFESSIONAL EDUCATION/DISCUSSION GUIDE

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 Spa at
PharmacovigilanceMalta@sanofi.com



- Discuss the information below pertaining to the following risks with the patients
- 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:	



Complete Blood Count (CBC)

- Risk of decreased blood cells (affecting mainly white blood cells)
- Complete CBC before treatment initiation and periodically during treatment based on signs and symptoms

Blood pressure

- 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
- Symptoms of liver disease
- Need to contact their doctor in case symptoms develop



- Risk of (serious opportunistic) infections
- Need to contact their doctor in case symptoms of infection develop
- Consider an accelerated elimination procedure in case of a serious infection
- Need to contact their doctor in case other medicines are taken that might affect the immune system



- Pregnancy should be excluded
- Need for effective contraception and to inform their doctor immediately if they stop contraception, or prior to changing contraceptive measures
- Aubagio should be discontinued in case of pregnancy
- Consider accelerated elimination procedure

DISCUSS

HAND-OVER

Patient Card:

- Provide the patient with the patient card and discuss the content regularly during each consultation **at least annually during treatment**
- Educate the patient 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 symptoms of **liver problems and infection** discussed in the Patient Card
- Discuss during each consultation the continued need for effective contraception during treatment
- 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.

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

Prescriber's name:

Prescriber's signature