

# 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**

- Physicians are asked to report any suspected adverse reactions via the national reporting system

**In case of any drug related adverse events, please contact:**

**The National Pharmacovigilance Centre - Saudi Food and Drug Authority (SFDA)**

**Call Center: 19999**

**E-mail: [npc.drug@sfda.gov.sa](mailto:npc.drug@sfda.gov.sa)**

**Website: <https://ade.sfda.gov.sa>**



**For SANOFI Pharmacovigilance center, please contact:+966-544-284-797**

**E-mail: [Ksa\\_pharmacovigilance@sanofi.com](mailto:Ksa_pharmacovigilance@sanofi.com)**

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

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

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

## AUBAGIO(teriflunomide) 14mg 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:



## 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 teriflunomide and to contact doctor immediately in case of pregnancy
- Consider a faster elimination process
- Report any pregnancy case to Sanofi by calling number: +966 54 428 4797 or email: [ksa\\_pharmacovigilance@sanofi.com](mailto:ksa_pharmacovigilance@sanofi.com) irrespective of adverse outcomes observed
- For information regarding the measurement of teriflunomide plasma concentration, please contact Sanofi on [ksa.medicalinformation@sanofi.com](mailto:ksa.medicalinformation@sanofi.com)

## Parents/caregivers of female child

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