accord

ACH-TERIFLUNOMIDE HEALTHCARE PROFESSIONAL EDUCATION/DISCUSSION GUIDE: CANADA

PATIENT'S NAME:	PATIENT'S AGE:
DATE OF FIRST VISIT:	PATIENT'S GENDER: ☐MALE ☐FEMALE
DATE FIRST PRESCRIBED:	TODAY'S DATE:

Discuss

- **Discuss the following risks with the patient/parent/caregiver, explain the monitoring requirements and tell them what they should do if patients experience specific signs or symptoms**
- **Please read the Product Monograph for full prescribing information**

Risk of haematological effects
- Risk of decreased blood cells (affecting mainly white blood cells)
- Full blood count before treatment initiation and thereafter if necessary, based on clinical signs or symptoms during treatment

Risk of hypertension
- Check blood pressure before treatment initiation and periodically during treatment
- Blood pressure elevation should be appropriately managed before and during treatment

Risk of liver effects
- Obtain transaminase and bilirubin levels within 6 months before initiation of ACH-TERIFLUNOMIDE therapy. Monitor ALT levels at least monthly for at least six months after starting ACH-TERIFLUNOMIDE.
- Patients should be counselled on the signs and symptoms of liver effects and told to contact their doctor immediately if any develop

Risk of serious infections including progressive multifocal leukoencephalopathy (PML)
- Screen patients for latent tuberculosis infection
- Patients should be told to contact their doctor immediately if they have any signs or symptoms of an infection
- Patients should also inform their doctor if they are prescribed or taking any other medicines that affect the immune system
- Consider an accelerated elimination procedure in case of a serious infection

Risk of teratogenicity
- Inform women of childbearing potential (WOCBP) that teriflunomide can cause serious birth defects so it is contraindicated in pregnancy, and they must use effective contraception during and after treatment until their teriflunomide blood levels are low. Women should contact their doctor immediately if they plan to conceive, stop or change contraception during this time.
- Check the potential for pregnancy in all female patients before and during treatment by obtaining a negative pregnancy test.
- Tell the parents/carers of girls that they should contact their doctor for counselling on the risk of teratogenicity and contraceptive advice when she starts to menstruate
- Women should contact their physician immediately and stop teriflunomide if they become pregnant. Physicians will: discuss and consider the accelerated elimination procedure, and encourage enrolment in the pregnancy registry. Information on the ACH-Teriflunomide Pregnancy Registry is available at www.accordhealth.ca or is available by calling 1-866-296-0354.

Counsel & Hand-Over

Patient Card:
- Provide the patient with the patient card and discuss the content regularly during each consultation and **at least annually during treatment**
- Complete your contact details on the patient card and replace it as necessary
- Educate the patient to show this card to any doctor or healthcare professional involved in medical care (e.g. in case of an emergency)
- Advise the patient to contact their prescriber or general practitioner if they develop any signs or symptoms of the risks discussed in the patient card
- Counsel and inform before treatment and regularly thereafter WOCBP including adolescents/their parents/caregivers about potential risk for the foetus
- Ensure adequate monitoring of patients when new prescriptions are issued including adverse reaction checks, and risk assessments and prevention

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

Prescriber's name: _____

Prescriber's signature: _____

Suspected adverse reactions should be reported to Accord Healthcare Inc at 1-866-296-0354 or at safety@accordhealth.ca.

Suspected adverse drug reactions (ADRs) can also be reported to the Health Canada at **https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html.**

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.