accord

ACH-Teriflunomide Pregnancy Registry Study to Monitor Teratogenicity

To monitor teratogenicity, Accord Healthcare Inc. has established the ACH-Teriflunomide Pregnancy Registry Study to collect information about the effect of teriflunomide exposure during pregnancy.

Serious Warnings and Precautions

Risk of Teratogenicity

Based on animal data, teriflunomide may cause major birth defects if used during pregnancy. Pregnancy must be excluded before starting ACH-TERIFLUNOMIDE. ACH-TERIFLUNOMIDE is contraindicated in pregnant women or women of childbearing potential who are not using reliable contraception. Pregnancy must be avoided during ACH-TERIFLUNOMIDE treatment or prior to the completion of an accelerated elimination procedure after ACH-TERIFLUNOMIDE treatment.

ACH-Teriflunomide is contraindicated in patients who are pregnant or women of childbearing potential not using reliable contraception. Teriflunomide may cause fetal harm when administered to a pregnant woman. Pregnancy must be excluded before start of treatment.

Patients who have become pregnant or suspect they could be pregnant while taking ACH-TERIFLUNOMIDE or up to two years after discontinuing ACH-TERIFLUNOMIDE treatment should contact their healthcare professional. Physicians are encouraged to enroll pregnant women in the Pregnancy Registry Study, or pregnant women may enroll themselves in the Pregnancy Registry Study by calling 1-844-822-2673, and can access the registry study details and educational materials at the following website www.accordhealth.ca.

ACH-Teriflunomide Pregnancy Registry Study Details:

- Objective: The purpose of the ACH-Teriflunomide Pregnancy Registry Study in pregnant women is to continuously monitor, evaluate, and assess for major and minor teratogenic effects.
- Study Type: Observational registry study (Targeted Follow-up Questionnaires to be used for data collection). ACH-Teriflunomide Pregnancy Registry is a 10-year observational registry study.
- Patient Population:
  - **Inclusion Criteria:**
    - Pregnant women (**with or without MS** themselves, such as in the case of having a male partner with MS taking teriflunomide) who have suspected or confirmed exposure to teriflunomide **at any dose,** for any number of days, and at any time during pregnancy. This includes pregnancy within 2 years of teriflunomide discontinuation if accelerated elimination was not used, or within 11 days of teriflunomide discontinuation if accelerated elimination was used; pregnant individuals who are or were taking teriflunomide or who were suspected to have teriflunomide exposure via the semen of a male partner taking teriflunomide; and, patients who have provided their consent to enroll in the Study.
    - Eligible participants for this registry-based observational study are patients who have confirmed or suspected exposure to ACH-Teriflunomide at any dose during pregnancy. These would include patients who became pregnant within two (2) years of ACH-Teriflunomide discontinuation if accelerated elimination was not used or within 11 days of ACH-Teriflunomide discontinuation if accelerated elimination was used. Also included are pregnant women suspected of having ACH-Teriflunomide exposure via the semen of a male partner taking ACH-Teriflunomide.
    - Patients who have provided their consent to enroll in the Study.
    - Sex/Gender: Female
    - Ages: Child, Adult, Older Adult

- Enrollment process of Pregnant Women and collecting informed consent: The patient will receive medical counseling from their HCP regarding ACH-Teriflunomide. The patient will be informed of the Pregnancy Registry Study and will have the option to voluntarily enroll via informed consent. HCPs will enroll pregnant women in the Pregnancy Registry Study. Pregnant women may enroll themselves in the Pregnancy Registry Study.
- Data Collection: HCPs will be advised to follow up with the patient during pregnancy and collect information about her pregnancy using the "ACH-Teriflunomide Exposure in Pregnancy Form". HCPs will also be advised to collect information regarding the infant a week after the delivery, and at 6, 12, and 24 months post-delivery using the "Infant Follow Up Form".

For quick reference of documents related to ACH-Teriflunomide, QR Codes are provided below:

Product Monograph

Patient Medication Information

Educational Materials:

ACH-Teriflunomide Healthcare Professional Education/Discussion Guide

ACH-Teriflunomide Patient Card

ACH-Teriflunomide Patient Education Brochure

ACH-Teriflunomide Pregnancy Registry Study Consent Form

ACH-Teriflunomide Pregnancy Registry Questionnaires (which include the ACH-Teriflunomide Exposure in Pregnancy Form and Infant Follow Up Form)