PATIENT INFORMATION AND CONSENT FORM
ACH-Teriflunomide Pregnancy Registry Study

Introduction:
You are being invited to participate in the ACH-Teriflunomide Pregnancy Registry Study, which has been established to collect information about the effect of teriflunomide exposure during pregnancy.

Before deciding to participate, you should clearly understand the study and its requirements. This document provides information about the study. Please read it carefully. If you decide to participate, you will be asked to provide us your doctor's details and sign this form.

Description and Purpose of the ACH-Teriflunomide Pregnancy Registry Study:
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. 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 will be included.

This study is an observational registry study. Data Collection will be done through Targeted Follow-up Questionnaires completed by your Healthcare Professional. Your Healthcare Professional will be advised to follow-up with you during pregnancy and collect information about your pregnancy using the "Teriflunomide Exposure in Pregnancy Form". Your Healthcare Professional 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".

What does your participation require?:
In order to collect data for this study from your Healthcare Professional, we require informed patient consent to contact your Healthcare Professional to obtain further information. By providing patient consent for this Pregnancy Registry Study, you are allowing SRX Solutions Inc on behalf of Accord Healthcare Inc. to follow up with your Healthcare Professional for pregnancy outcome and at intervals of 1 week, 6, 12 and 24 months post-delivery.

The data collected will be stored at SRX Solutions Inc. and will be shared with Accord Healthcare Inc., with third parties who act for or on behalf of Accord Healthcare Inc. and with regulatory/health authorities (ex. Health Canada) for further processing for this pregnancy registry study. This may also include reporting adverse events to regulatory authorities.

Voluntary Participation and/or Withdrawal:
Your participation in this study is voluntary.
You may refuse to participate or you may discontinue your participation at any time without explanation.

Questions and Contact Information:
If you have any questions about this study, you can contact SRX Solutions Inc. at 1-844-822-2673, or Accord Healthcare Inc. at 1-866-296-0354, or safety@accordhealth.ca.

PATIENT CONSENT FORM

By providing informed patient consent for this Pregnancy Registry Study, you (or Legal Representative on behalf of the patient) hereby agree and consent that SRX Solutions Inc on behalf of Accord Healthcare Inc. may collect, use, disclose, share and process personal data (including but not limited to sensitive personal data) submitted in this form and/or otherwise provided to us for the purposes of complying with the obligation under applicable laws to monitor the safety of medicines and for responding to medical information queries. Any data obtained would be stored at SRX Solutions Inc and will be shared with Accord Healthcare Inc. who is the Marketing Authorization Holder (HAH) for the product.

The information will be used for the purpose of drug safety surveillance and to enable SRX Solutions Inc. to deal with your enquiry, this may be shared with regulatory authorities or other health agencies. Your de-identified personal data (including but not limited to sensitive personal data) may also be transferred to third parties who act for or on behalf of the Marketing Authorization Holder, Accord Healthcare Inc., for further processing in accordance with the purpose(s) for which the data were originally collected. You have the right of access to your personal data which we hold about you. If you have any questions regarding your personal data for this pregnancy registry study, you can call SRX Solutions Inc. at 1-844-822-2673.

By submitting this form, you also expressly consent to the transfer of your personal data (including but not limited to sensitive personal data) and the processing of such data within and outside Canada.

At any time and subject to applicable laws, you may exercise the rights of access, rectification, cancellation, opposition and revoke your consent to use, disclose, transfer and process of your personal data. This can be done by calling 1-844-822-2673.

I hereby provide consent for SRX Solutions Inc on behalf of the Marketing Authorization Holder, Accord Healthcare Inc., to contact treating physician for further details regarding the pregnancy, infant follow-up and reported event with my medication.

Patient Signature		Date	

Doctor's Contact Details	
Doctor's Name:	
Address:	
Postal Code:	
Phone / Fax No.	
Email ID:	

Patient / Legal Representative details	
First & Last Name	
Phone / Fax No.	
Email ID:	