What will participation involve if I (or my loved one) decide to enroll in the study?

After you or your loved one are enrolled in the study, a study representative will be in contact at select time points to collect pregnancy-related health information. If currently pregnant, you or your loved one will be contacted once during each trimester, and around the time of estimated delivery date or when you or your loved one give birth.

If you or your loved one provide consent, a study representative will also contact your/their healthcare provider(s) at two time points during the study: approximately at week 34 for prenatal follow-up and around the time of estimated delivery date, or when you or your loved one give birth.

In addition, a study representative will contact your/their infant's pediatrician at four time points during the study: when the baby is 3, 6, 9, and 12 months of age.

Will my (or my loved one's) privacy be protected?

All personal and medical information will be kept strictly confidential. Information about your or your loved one's health while enrolled in the EPIDIOLEX Pregnancy Surveillance Program will be kept anonymous and any identifying information will not be used. Patient names will be coded and not identifiable to the sponsor (Jazz).

To speak to a study representative, contact the

EPIDIOLEX® Pregnancy Surveillance Program

toll-free at: 855-272-7158

Hours of Operation:
M - F 9:00am-5:00pm, EST

For more information visit:
www.epidiolexpregnancystudy.com

EPIDIOLEX® Pregnancy Surveillance Program

Caregiver and Patient Information Pamphlet

What is a Pregnancy Surveillance Program?

During the development of medical products, women who are pregnant are typically excluded from clinical trials, and therefore, limited information is available on the use of medications during pregnancy. The US Food and Drug Administration (FDA) mandates pharmaceutical companies to monitor use of many different medications during pregnancy, to provide further information. Guidance was issued by the FDA in 2019 for pharmaceutical companies on pregnancy studies, including pregnancy surveillance programs.

EPIDIOLEX®
Pregnancy Surveillance
Program

What is the EPIDIOLEX® Pregnancy Surveillance Program and why is it being initiated?

Following the 2019 FDA guidance, Jazz Pharmaceuticals Research UK Limited, the manufacturer of EPIDIOLEX® (cannabidiol), is conducting this observational study to evaluate pregnancy-related health outcomes in women who have taken at least 1 dose of EPIDIOLEX in the 13 days before their last menstrual period prior to pregnancy or anytime during pregnancy and their babies up to 12 months of age who were exposed to at least 1 dose of EPIDIOLEX in utero. Participants will be asked to provide health information about their pregnancy and their infant's growth and development up to their first birthday.

Participation in this study will not impact maternal or infant standard treatment or care as decided by healthcare providers.

There is another pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antiepileptic drugs (AEDs), such as EPIDIOLEX, during pregnancy using a different study design. The North American Antiepileptic Drug (NAAED) Pregnancy Registry is a separate study. It is possible to participate in both studies, or to participate in only one study. You or your loved one may also choose not to participate in either study.

Why should I (or my loved one) participate in this study?

The information collected in this study will be provided to the FDA so that other women who become pregnant while being treated with EPIDIOLEX can better understand any potential effects of EPIDIOLEX on their pregnancy and their babies.

By participating in this study, you or your loved one will provide important information that will help Jazz Pharmaceuticals Research UK Limited evaluate pregnancy-related health outcomes. You or your loved one can also choose whether your physician can provide information as well.

The decision to participate in this study is entirely voluntary. While enrolled in the study, personal and medical information will be kept strictly confidential.

Am I (or my loved one) eligible to participate in the study?

If you or your loved one has taken at least 1 dose of EPIDIOLEX in the 13 days before the last menstrual period prior to pregnancy or any time during pregnancy, you may be eligible to participate in this study. You can enroll even if you or your loved one are no longer pregnant.

How do I (or my loved one) participate in this study?

To learn more about the EPIDIOLEX Pregnancy Surveillance Program and to find out if you or your loved one are eligible to participate, please contact a study representative at 855-272-7158. You or your loved one may also ask your healthcare provider for a referral.

A study representative will describe the study in more detail, answer any of your questions and ask for verbal consent along with an optional written release of medical records. Consent acknowledges understanding of the study, and release of relevant medical records allows you/your loved one's and infant's healthcare information to be collected. If you or your loved one provide consent, a study representative will contact your/their healthcare provider to confirm personal health information.