



BREXAFEMME® Pregnancy Safety Study

This booklet contains information about the BREXAFEMME® Pregnancy Safety Study for women who may have taken BREXAFEMME® at any time during pregnancy or whose conception is estimated to have happened within four days after receiving the last dose of BREXAFEMME®. This booklet should help you decide whether you or someone you know may want to participate in the safety study. The aim of the study is to gain knowledge about the health of pregnant women and their babies.

How can I take part in the safety study?

You can enroll in the study in any of the following ways:

- Please fill out the form in the <u>Contact me (patient)</u> for registration information and the study representative will get in touch with you after getting your information.
- Call the number 1-888-982-7299 and speak to the safety study staff member.
- Contact your healthcare provider, with your consent they can help get you enroll on their behalf.







What is BREXAFEMME® Pregnancy Safety Study?

This BREXAFEMME® Pregnancy Safety Study is a study for women who may have received BREXAFEMME® at any time during pregnancy or whose conception is estimated to have happened within four days after receiving the last dose of BREXAFEMME®.

The purpose of this study is to monitor and learn about the health of women who have taken BREXAFEMME® during pregnancy and the health of their babies. The study will observe participants throughout pregnancy and monitor the health of babies until the age of 12 months.

The information collected throughout the study will help us learn more about the use of BREXAFEMME® (ibrexafungerp) during pregnancy and may help other women who may be exposed to BREXAFEMME® in the future.

What will I have to do?

If you are willing to take part in the safety study, you will be asked to give informed consent. Informed consent means that you receive information about what the safety study is, have a chance to ask any questions, and then agree that you want to participate in the study.

Any questions you may have will be addressed by a study representative in a telephone interview. If you give your consent, you will be contacted at regular pre-defined intervals by representatives from the time you join the safety study until your baby is about 12 months old.

If you take part in the safety study, you will not have to:

- attend any extra doctor visits
- take any extra medical tests
- take additional medications

Who can participate?

You may be eligible if:

- you are exposed to ibrexafungerp during pregnancy or,
- conception is estimated to have occurred within 4 days after the last dose of ibrexafungerp.

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When will I be contacted during study?

- At the time of enrollment: To collect some information about you and your pregnancy via telephone.
- At the end of each trimester during your pregnancy:
 To check if there have been any changes in your pregnancy, and general health, the medicines you are taking, or any changes to your contact information.
- About 4 weeks after your expected delivery date, and when your baby is approximately 6 months and 12 months old.

Why and when my/baby's healthcare providers will be contacted?

With your consent, a study representative will contact the healthcare provider monitoring you during your pregnancy, and your baby's healthcare provider. These contacts will be done to collect information about your general health during pregnancy, and your baby's health. Below is the schedule of contacts that will be made by the representative:

- To your healthcare provider twice during your pregnancy, that is, at the time of enrollment and at the end of 2nd trimester, and then about 4 weeks after you have given birth.
- To your baby's healthcare provider about 4 weeks after you have given birth, and when your baby is 6 and 12 months old to ask about the health of your baby.





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If you would like more information, please contact us:

Contact number 1-888-982-7299