Who can take part?

You may be able to take part if you are pregnant, and agree for your doctor and your baby's doctor to provide information about your pregnancy, delivery, and your health and your baby's health to the registry team. You also need to either:

- have taken Orilissa® (elagolix tablets) at any time after your last menstrual period, **or**
- have not taken Orilissa® but have endometriosis.

What else do I need to consider?

- You do not have to take part in the registry if you don't want to.
- If you choose to take part in the registry, you can stop participating at any time.
- The telephone calls that participants will have with the registry team are expected to last for 10–15 minutes per call, with the exception of the first call, which may take up to 45 minutes.
- You will not be required to take any medications or have any additional visits that are not part of your regular care to take part in the registry.

How do I get more information?

To find out more, contact the registry team using the information provided here. Registry participation is voluntary. By contacting the registry team, you are under no obligation to take part in the registry.

You may call the registry team at **1-(833)-782-7241**

or visit the website **www.bloompregnancyregistry.com**

To review Full Prescribing Information including BOXED WARNING and Medication Guide for Orilissa®, visit www.rxabbvie.com or contact AbbVie Medical Information at 1-(800)-633-9110

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Sharing your experience with endometriosis and pregnancy

Consider joining this registry so that we may learn more about endometriosis medications and pregnancy

Patient Information

BLOOM Pregnancy Registry

Supported by AbbVie Clinical Development Operations

What is an observational study?

The purpose of an observational study (a type of medical research study) is to learn more about approved medications and how they are used.

When choosing whether to take part in an observational study or registry, like the BLOOM Pregnancy Registry, it is important to understand why the study is taking place and what will happen if you participate.

If you take part in the BLOOM Pregnancy Registry, you and your doctor will be asked to share information with the registry team from your routine doctor appointments and your baby's doctor appointments, and other relevant information about your lifestyle. Your personal information, such as your age and year of birth, together with any health information collected about you or your baby during the registry, will be kept private. You will not need to attend any additional medical appointments to take part in the registry or take any additional medications (other than those you would usually take).

This brochure contains information that may help you decide if you want to take part in the BLOOM Pregnancy Registry.

Do not take Orilissa® if you are pregnant or trying to become pregnant. It may increase the risk of early pregnancy loss. If you think you are pregnant, stop taking Orilissa® right away and call your health care provider.

About the BLOOM Pregnancy Registry

This registry was created to help doctors better understand if medications containing elagolix, like Orilissa® (elagolix tablets), have any effect on pregnancy, delivery, or the health of babies. If you have endometriosis, you do not need to have taken Orilissa® to take part in this registry. Orilissa® (elagolix tablets) should not be taken by women who are pregnant, or planning to become pregnant.

Orilissa® may change the menstrual cycle and make it hard for women to know if they are pregnant. Women taking Orilissa® should watch for other signs of pregnancy such as breast tenderness, nausea, or fatigue.

Why is the BLOOM Pregnancy Registry important?

Often when a woman receives a medication, the effect of that medication on the health of her baby is not known. This is because pregnant women are often prohibited from participating in studies when possible new medications are being tested. Pregnancy registries are designed to help health care providers learn more about medications and the potential effects on babies.

What will the BLOOM Pregnancy Registry involve?

If you take part, you will be in the registry throughout your pregnancy and for up to 1 year after your delivery. You will need to:

- talk to the registry team on the telephone and answer questions about your health, lifestyle, pregnancy, and your baby's health
- agree for your doctor and your baby's doctor to give information about your health, pregnancy, and delivery, and information on your baby's health, to the registry team.