# Elagolix (Orlissa®)

This sheet is about exposure to elagolix in pregnancy and while breastfeeding. This information is based on published research studies. It should not take the place of medical care and advice from your healthcare provider.

## *What is elagolix?*

Elagolix is a gonadotropin-releasing hormone antagonist medication. It has been used to treat pain associated with endometriosis (a condition where tissue, that is like the inner lining of the uterus, grows outside the uterus). A brand name for elagolix is Orlissa®. Elagolix is also sold as a combination medication with estradiol and norethisterone. This medication is called Oriahnn®.

Sometimes when women find out they are pregnant, they consider changing how they take their medication or stopping it altogether. However, it is important to talk with your healthcare providers before making any changes to how you take your medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

The product label for elagolix recommends that this medication not be used in pregnancy due to possible concerns with miscarriage. It also suggests caution when using this medication during breastfeeding. However, the benefit of using elagolix may outweigh possible risks. Your healthcare provider can talk with you about using elagolix and what treatment is best for you.

## *I am taking elagolix, but I would like to stop taking it before getting pregnant. How long does the drug stay in my body?*

The time it takes the body to metabolize (process) medication is not the same for everyone. In healthy, non-pregnant adults, it takes up to 36 hours, on average, for most of the elagolix to be gone from the body.

## *I take elagolix. Can it make it harder for me to get pregnant?*

Elagolix can lower the body's levels of luteinizing hormone (LH) and follicle-stimulating hormone (FSH). These hormones are important for ovulation (when an ovary releases an egg. This can make it harder to get pregnant.

## *Does taking elagolix increase the chance of miscarriage?*

Miscarriage is common and can occur in any pregnancy for many different reasons. It is not known if elagolix can increase the chance of miscarriage in humans.

Animal studies with very high doses of elagolix reported more pregnancy losses. However, animal studies do not always predict what will happen in humans, especially when animals are given much higher doses than those given to humans. A clinical trial looking at 453 human pregnancies exposed to elagolix, estradiol, and norethisterone did not report an increased chance of miscarriage.

The product label for this medication reported miscarriages when elagolix during pregnancy. However, the number of miscarriages was not higher than what would be expected in the general population. Also, some health conditions, such as endometriosis, can increase the chance of miscarriage.

## *Does taking elagolix increase the chance of birth defects?*

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at research studies to try to understand if exposure, like elagolix, might increase the chance of birth defects in a pregnancy.

It is not known if elagolix can increase the chance of birth defects. Clinical trial data on 49 pregnancies exposed to elagolix reported no increased chance of birth defects.

## *Does taking elagolix in pregnancy increase the chance of other pregnancy-related*

### *problems?*
It is not known if elagolix can increase the chance of pregnancy-related problems such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth). Clinical trial data on 49 pregnancies exposed to elagolix reported no changes in birth weight. Studies have not been done to look at the chance of other pregnancy complications after elagolix use.

### *Does taking elagolix in pregnancy affect future behavior or learning for the child?*
Studies have not been done to see if elagolix can increase the chance of behavior or learning issues for the child.

### *Breastfeeding while taking elagolix:*
There is no information available on the use of elagolix while breastfeeding. It is not known if elagolix passes into breast milk, or what side effects, if any, a child might have when exposed to elagolix through breast milk. Be sure to talk to your healthcare provider about all your breastfeeding questions.

### *If a man takes elagolix, could it affect fertility or increase the chance of birth defects?*
Typically, elagolix is not prescribed to men. Studies have not been done to see if elagolix could affect male fertility (ability to make healthy sperm) or increase the chance of birth defects. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Please click here for references.



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