

Pevexa

The safety of paroxetine mesylate (pevexa) during pregnancy or breastfeeding

The information provided below is for readers based in the United States of America. Readers outside of the United States of America should seek the information from local sources.

THIS MEDICATION CAN CAUSE HARM TO YOUR BABY:

Paroxetine may be associated with an increased risk of heart defects if used during the first trimester of pregnancy. It is important to weigh the risks versus benefits before continuing this medication during pregnancy.

What is paroxetine?

Paroxetine is an antidepressant known as a selective serotonin reuptake inhibitor (SSRI). SSRIs help to alleviate symptoms of anxiety and depression.

What is paroxetine used to treat?

Paroxetine is a prescription medication used to treat depression, anxiety, obsessive-compulsive disorder, and panic disorder.

How does paroxetine work?

SSRIs such as paroxetine increase the presence of the neurotransmitter serotonin in the brain, which can improve symptoms of depression and anxiety.

If I am taking paroxetine, can it harm my baby?

Paroxetine crosses the human placenta to reach the developing baby. Animal studies suggest paroxetine may be associated with facial defects. Animal studies with doses several times greater than human doses found no increased risk of birth defects; however, additional animal studies found low birth weights and behavioral changes in the baby. Although human studies have produced conflicting results, many show paroxetine is associated with an increased risk of birth defects including heart defects, especially during the first trimester. Many studies associate paroxetine with a greater risk

for birth defects compared to other SSRIs. Some additional studies have identified an association between paroxetine exposure in utero and problems with skull development, autism (2nd or 3rd trimester exposure), and clubfoot. Exposure to paroxetine may increase the risk of spontaneous abortion (miscarriage), low oxygen levels due to persistent pulmonary hypertension (2nd or 3rd trimester exposure), prematurity, neurodevelopmental delay, difficult neonate to infant transition, and need for special care. Neonatal behavioral syndrome is a possible side effect from paroxetine use in late pregnancy. It is characterized by mild changes in neurologic, motor, respiratory, and gastrointestinal behaviors of the newborn that resolve within 2 weeks.

If I am taking paroxetine and become pregnant, what should I do?

It is important that depression and anxiety therapy be individualized for each patient. The risks should be weighed against the benefits of continuing antidepressant therapy during pregnancy. Uncontrolled depression or anxiety can cause negative side effects in both mother and baby. Women who are attempting to conceive or become pregnant while on paroxetine should speak with their doctor. Other antidepressants and/or therapy are preferred over paroxetine during pregnancy. It is generally recommended to discontinue paroxetine or switch to another antidepressant medication during pregnancy. Your doctor can always restart antidepressant therapy following delivery if it is discontinued during pregnancy. Women who continue paroxetine or who are accidentally exposed to paroxetine during pregnancy should receive counseling on potential risks to the baby. The American College of Obstetricians and Gynecologists recommends ultrasound of the developing baby's heart in women who are exposed to paroxetine early in pregnancy.

If I am taking paroxetine, can I safely breastfeed my baby?

Paroxetine is excreted through the breast milk. An infant is exposed to less than 5.6% of the mother's dose. No adverse events from paroxetine exposure through breast milk have been reported, but it is unknown how exposure could affect long-term neurobehavioral development. One small study found a low frequency and mild severity of adverse events in breastfeeding infants exposed to paroxetine. It is recommended to either discontinue paroxetine during breastfeeding or discontinue breastfeeding if continuing paroxetine. If a woman takes this medication while breastfeeding, her doctor may recommend stopping or decreasing the frequency of breastfeeding because of the unknown neurobehavioral effects. SSRIs have been associated with affects on maternal lactation. Mothers taking paroxetine and breastfeeding their babies should be monitored, and they may require breastfeeding support. The American Academy of Pediatrics states that antidepressants such as paroxetine pose some risk to the breastfeeding infant.

If I am taking paroxetine, will it be more difficult to get pregnant?

Paroxetine and other SSRIs are associated with reduced sex drive and inability to orgasm, which could make it harder to get pregnant.

If I am taking paroxetine, what should I know?

It is important to speak with your doctor to determine if you should continue paroxetine therapy during pregnancy. It is not recommended to start a new antidepressant such as paroxetine during pregnancy. Paroxetine should only be used during pregnancy if the benefits to the mother outweigh the risks to the developing baby. There is an increased risk of birth defects, particularly heart defects, with first trimester use of this medication. Exposure during the third trimester may cause complications in the baby such as irritability and difficulty feeding. Breastfeeding mothers who are taking paroxetine should monitor their baby for any adverse effects.

If I am taking any medication, what should I know?

This report provides a summary of available information about the use of paroxetine during pregnancy and breastfeeding. Content is from the product label unless otherwise indicated.

You may find Pregistry's expert report about depression [here](#), reports about other mental health disorders [here](#), and reports about the individual medications used to treat mental health disorders [here](#). Additional information can also be found in the resources below.

For more information about **paroxetine** during and after pregnancy, contact <http://www.womenshealth.gov/> (800-994-9662 [TDD: 888-220-5446]) or check the following link:

U.S. Food and Drug Administration: [Pevexa Prescribing Information](#)

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General information

It is very common for women to worry about having a miscarriage or giving birth to a child with a birth defect while they are pregnant. Many decisions that women make about their health during

pregnancy are made with these concerns in mind.

For many women these concerns are very real. As many as 1 in 5 pregnancies end in a miscarriage, and 1 in 33 babies are born with a birth defect. These rates are considered the background population risk, which means they do not take into consideration anything about the health of the mom, the medications she is taking, or the family history of the mom or the baby's dad. A number of different things can increase these risks, including taking certain medications during pregnancy.

It is known that most medications, including over-the-counter medications, taken during pregnancy do get passed on to the baby. Fortunately, most medicines are not harmful to the baby and can be safely taken during pregnancy. But there are some that are known to be harmful to a baby's normal development and growth, especially when they are taken during certain times of the pregnancy. Because of this, it is important to talk with your doctor or midwife about any medications you are taking, ideally before you even try to get pregnant.

If a doctor other than the one caring for your pregnancy recommends that you start a new medicine while you are pregnant, it is important that you let them know you are pregnant.

If you do need to take a new medication while pregnant, it is important to discuss the possible risks the medicine may pose on your pregnancy with your doctor or midwife. They can help you understand the benefits and the risks of taking the medicine.

Ultimately, the decision to start, stop, or change medications during pregnancy is up to you to make, along with input from your doctor or midwife. If you do take medications during pregnancy, be sure to keep track of all the medications you are taking.