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Paroxetine (Paxil[®]) and Pregnancy

This sheet talks about the risks that exposure to paroxetine can have during pregnancy. With each pregnancy, all women have a 3% to 5% chance of having a baby with a birth defect. This information should not take the place of medical care and advice from your health care provider.

What is paroxetine?

Paroxetine is a medication used to treat depression, social anxiety disorder, obsessive compulsive disorder, and panic disorder. Paroxetine belongs to the class of antidepressants known as selective serotonin reuptake inhibitors or SSRIs. A common brand name for paroxetine is Paxil[®].

I am taking paroxetine, but I would like to stop taking it before becoming pregnant. How long does paroxetine stay in my body?

While everyone breaks down medication at a different rate, on average it takes four to five days for most of the paroxetine to be gone from the body after taking the last dose. If you choose to stop taking paroxetine, the dosage should be gradually lowered before quitting completely to prevent withdrawal symptoms. Please discuss the benefits and risks of stopping your medication with your health care provider.

Can taking paroxetine make it more difficult for me to become pregnant?

We do not know if taking paroxetine will make it harder for you to become pregnant. Animal studies suggest a reduced pregnancy rate with the use of paroxetine as a result of decreased male fertility. However, there are no reports linking paroxetine to human infertility or an inability to become pregnant.

Can taking paroxetine during my pregnancy cause birth defects?

Early studies looking at paroxetine use during pregnancy found no increased risk for birth defects. Since 2005, a few studies have suggested that exposure to paroxetine may be associated with an increased risk for heart defects. In the general population the background risk for heart defects is one percent. These studies showed that paroxetine

use during pregnancy may increase this risk to two percent. Based on these studies, several organizations made statements saying that women should avoid taking paroxetine during pregnancy if possible. However, more recent studies have not found an increased risk for heart defects with exposure to paroxetine during pregnancy. Overall, the majority of studies show that paroxetine is not associated with an increase in the risk for birth defects over what is normally seen in the general population.

I need to take paroxetine throughout my entire pregnancy. Will it cause withdrawal symptoms in my baby?

If you are taking paroxetine during the third trimester until the time of delivery, your baby may have some complications for the first few days of life. Symptoms of withdrawal such as problems breathing, jitteriness, increased muscle tone, irritability, altered sleep patterns, tremors and difficulty eating may occur. Your baby may need to stay in a special care nursery for several days until the withdrawal symptoms go away.

Are there any other problems paroxetine can cause when used in the third trimester?

One study showed that babies whose mothers take SSRIs like paroxetine during the third trimester may be at an increased risk for pulmonary hypertension, a serious lung problem at birth. You should inform your obstetrician and your baby's pediatrician that you are taking paroxetine so that any extra care can be readily provided.

Should I stop taking paroxetine when I find out I'm pregnant? What about weaning off paroxetine before the third trimester?

It is important to discuss with your doctor the risks associated with taking paroxetine during

pregnancy as compared to the risks of stopping paroxetine. Studies have shown that when depression is left untreated during pregnancy, there may be increased risks for miscarriage, preeclampsia, preterm delivery, low birth weight, and a number of other harmful effects on the mother and the baby. Only you and your doctor know your medical history and can best determine whether or not you should stop taking paroxetine during pregnancy. Some women can gradually wean off of paroxetine before 28 weeks; for other women, the effects from stopping paroxetine may be more harmful than the possible risks to the baby if they stay on paroxetine. The benefits of taking paroxetine for your specific situation and the potential risks to the baby should be considered before a decision is made.

Will taking paroxetine have any long-term effect on my baby's behavior and development?

There are no studies on the long-term development of infants exposed to paroxetine during pregnancy. However, two studies reported that another SSRI (fluoxetine) does not appear to have any significant long-term effects on brain development in babies exposed during pregnancy. Yet, since paroxetine is not structurally similar to fluoxetine (even though both are SSRIs), it is unclear whether this data can be applied. Long-term studies on infants exposed to paroxetine are needed before we will know if there are any effects on the fetal brain and on the baby's behavior and development.

Can I take paroxetine while breastfeeding?

Several studies have shown that one to two percent of the amount of paroxetine that the mother takes passes into the breast milk. There were no harmful effects in the breastfed infants in these studies. Long term studies on infants exposed to paroxetine in breast milk have not been conducted. Please talk to your pediatrician if you need to take paroxetine while breastfeeding.

What if the father of the baby takes paroxetine?

There are no studies looking at possible risks to a pregnancy when the father takes paroxetine. In general, medications the father takes do not increase the risk to a pregnancy because the father does not share a blood connection with the developing baby. For more information, please see the OTIS fact sheet *Paternal Exposures and Pregnancy*.

OTIS is currently conducting a study looking at women who take antidepressants during pregnancy and choose to continue or discontinue their medication. If you are interested in taking part in this study, please call 1-877-875-7333.

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If you have questions about the information on this fact sheet or other exposures during pregnancy, call OTIS at 1-866-626-6847.