



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Fluoxetine (Prozac®)

In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. This sheet talks about whether exposure to fluoxetine may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

What is fluoxetine?

Fluoxetine is a medication commonly used to treat depression. Fluoxetine is also used to treat obsessive-compulsive disorders, Tourette's syndrome, eating disorders (bulimia nervosa), panic disorder and Premenstrual Dysphoric Disorder (PMDD). Some brand names for fluoxetine are Prozac® and Sarafem®. Fluoxetine belongs to the class of antidepressants known as selective serotonin reuptake inhibitors (SSRIs).

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

Every person's ability to break down the medication is different. On average, in healthy adults, almost all of the fluoxetine would likely be gone from the body in a little over one month after stopping. However, studies have shown that the medicine levels are fairly low after one to two weeks. An active metabolite of fluoxetine, called norfluoxetine, can remain in the body for five to six weeks (about one and a half months) after taking the last dose. Always talk to your health care providers before stopping prescription medicine.

Can taking fluoxetine make it harder for me to become pregnant?

Animal studies have not shown any effect on fertility with the use of fluoxetine. Further studies are needed to determine fluoxetine's effect on fertility.

Does fluoxetine use increase the chance for miscarriage?

Several studies have not found a greater chance for miscarriage among women on fluoxetine.

Can taking fluoxetine during my pregnancy cause birth defects?

Unlikely. Fluoxetine is one of the better-studied antidepressants in pregnancy. There are reports on thousands of pregnancies exposed to fluoxetine during the first trimester. Studies have generally not found an increased chance for birth defects with fluoxetine use during pregnancy.

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

If you are taking fluoxetine during the third trimester until the time of delivery, your baby could have some problems. These symptoms or problems are called "neonatal adaptation syndrome" or NAS. The symptoms include irritability, crying, jitteriness, increased muscle tone, harder time breathing, altered sleep patterns, tremors (shivers) and/or trouble eating. In most cases, these symptoms are mild and go away within weeks with no treatment or with only supportive care. Most babies are not affected.

Are there any other problems with using fluoxetine in the third trimester?

More research is needed to answer this question. One study found that third trimester use of fluoxetine compared to first trimester use increased the chances for premature delivery (delivery before 37 weeks), higher rates of care in the newborn special-care nursery, and lower birth weight and length. In this study, women who stopped using fluoxetine by the end of the second trimester did not seem to have a higher chance for these problems. However, another study did not confirm these findings. In addition, studies have shown that prematurity and pregnancy

complications can be related to the maternal depressive disorder itself rather than to the medication exposure.

One study showed that babies whose mothers take SSRIs like fluoxetine during the second half of pregnancy might have a slightly higher chance for pulmonary hypertension, a serious lung problem at birth. The overall risk for this appears to be low. However, you should tell your medical team and your baby's pediatrician that you are taking fluoxetine so that any extra care can be readily provided.

Should I stop taking fluoxetine before the third trimester?

It is important to discuss with your health care provider any risks and benefits of taking fluoxetine during pregnancy as compared to stopping fluoxetine. Studies have shown that when depression is left untreated during pregnancy, there can be a higher chance for pregnancy complications such as miscarriage, preeclampsia, preterm delivery, low birth weight, and/or postpartum depression. Only you and your health care team know your history and can best decide if you should continue or stop taking fluoxetine during pregnancy.

Will taking fluoxetine have any effect on my baby's behavior and development?

Studies have begun to look at the possible long-term effects on infants exposed to fluoxetine during pregnancy. Fluoxetine affects the mother by changing chemical levels in the brain. In theory, these changes might also have an effect on fetal brain development. A few studies have looked at the development of children from 16 months to 7 years of age and did not find differences between exposed and unexposed children. Furthermore, one of these studies noticed that untreated depression might affect the child's IQ. These studies are reassuring; however, more studies are needed before we can be certain of the effects on the fetal brain.

Can I take fluoxetine while breastfeeding?

Fluoxetine and its metabolite, norfluoxetine, are found in breast milk. The amount of the medication that gets to the breastfed baby is usually less than ten percent of the amount found in the mother's blood.

There are several small studies and case reports regarding the use of fluoxetine during breastfeeding. Most found no problems in breastfed babies. In a small number of cases, irritability, vomiting, diarrhea, and less sleep, have been reported. One study also noted a chance for slightly less weight gain in infants exposed to fluoxetine in breast milk; however, this would likely only be of clinical significance if the infant's weight gain were already of concern.

One small study showed that babies whose mothers took fluoxetine while breastfeeding scored no differently on neurodevelopmental tests than other babies. More studies need to be done to determine if breastfeeding while taking fluoxetine causes any long-term effects on learning or behavior.

In newborns less than two months of age, fluoxetine might have a higher chance of causing a side effect compared to older babies. If this medication is the one that works the best for the mother, breastfeeding should not be discouraged. Instead, observe the baby for side effects and report to the pediatrician.

What if the father of the baby takes fluoxetine?

There are no studies looking at possible risks to a pregnancy when the father takes fluoxetine. In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

References Available By Request

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