

# Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)** For more information about us or to find a service in your area, call **(866) 626-6847**. Visit us online at **www.MotherToBaby.org**. Find us! Facebook.com/MotherToBaby or @MotherToBaby on Twitter

### Fluoxetine (Prozac®) and Pregnancy

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 obsessivecompulsive disorders, Tourette's syndrome, eating disorders (bulimia nervosa), and Premenstrual Dysphoric Disorder (PMDD). 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?

The liver breaks down fluoxetine. Every person's ability to break down the medication is different. On average, fluoxetine has a half-life (time it takes to eliminate one half of the drug from the body) of two to three days, but may be found in your system for several weeks after you stop taking it. Studies have shown that the levels are fairly low after one to two weeks. An active metabolite of fluoxetine called norfluoxetine has a half-life of seven to sixteen days, but can remain in the body for a much longer time period.

Please talk to your health care provider before you stop taking fluoxetine. The benefits of taking the medication for your specific situation, and any possible adverse outcomes of not taking it, should be discussed with your health care provider.

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

Animal studies have not shown any effect on fertility with the use of fluoxetine. There have been reports of lack of orgasm or delayed orgasm in women and men who take fluoxetine. There have also been reports of men and women who have had infertility problems after being treated with fluoxetine. Further studies are needed to determine fluoxetine's effect on fertility.

#### Can taking fluoxetine during my pregnancy cause birth defects?

Fluoxetine is one of the better-studied antidepressants in pregnancy. There are reports of over 2,000 pregnancies exposed to fluoxetine during the first trimester. Studies have generally not found an increased risk 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 may experience some complications for the first few days of life requiring extra care. Symptoms of withdrawal such as problems breathing, jitteriness, increased muscle tone, irritability, altered sleep patterns, tremors and difficulty eating may occur. In most cases, these symptoms are mild and disappear by two weeks of age with no treatment or with only supportive care. While these problems occur at all doses of fluoxetine, they may occur more often with higher doses of fluoxetine.

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

Further 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, 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 be at an increased risk for these problems. Another study did not confirm these findings. Studies have shown that prematurity and other pregnancy complications may 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 may be at an increased risk for pulmonary hypertension, a serious lung problem at birth. The risk for this appears to be low. You should inform your obstetrician 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 the risks associated with taking fluoxetine during pregnancy as compared to the risks of stopping fluoxetine. 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 health care provider know your medical history and can best determine whether or not you should stop taking fluoxetine during pregnancy. Some women can gradually wean off of fluoxetine before 28 weeks; for other women, the effects from stopping fluoxetine may be more harmful than the possible risks to the baby if they stay on fluoxetine. The benefits of taking fluoxetine for your specific situation and the potential risks to the baby should be considered before a decision is made.

#### 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. These changes could also have an effect on fetal brain development. Two studies examining development in children at 16 months to 7 years of age did not find differences between exposed and unexposed children. 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 breakdown product, 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 reports found no problems in breastfed babies. However, in a small number of cases, irritability, vomiting, diarrhea, and/or decreased sleep were seen in newborns. These symptoms were thought to be due to the mother's use of fluoxetine while breastfeeding. One study also noted a slight decrease in weight gain; however, this decrease would likely only be significant 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.

Other antidepressants like paroxetine or sertraline get into breast milk in lower amounts than fluoxetine and therefore may be better to use while breastfeeding. Be sure to talk to your health care provider about all your choices for breastfeeding.

#### 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. As stated earlier, fluoxetine could pose some infertility problems in the male. 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 http://www.mothertobaby.org/files/paternal.pdf.

#### **References Available By Request**