

Fluoxetine (Prozac®)

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

What is fluoxetine?

Fluoxetine is a medication that has been used to treat depression, obsessive-compulsive disorder (OCD), Tourette's syndrome, bulimia nervosa, panic disorder, and premenstrual dysphoric disorder (PMDD). Fluoxetine has also been used to treat body dysmorphic disorder, hot sweats, posttraumatic stress disorder (PTSD), and Raynaud's phenomenon. Some brand names for fluoxetine are Prozac®, Prozac Weekly®, Rapuflux®, Selfemra®, and Sarafem®. Fluoxetine belongs to the class of antidepressants known as selective serotonin reuptake inhibitors (SSRIs).

Sometimes when women find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take your medication. Stopping this medication suddenly can cause some people to have withdrawal symptoms. It is not known if or how withdrawal might affect pregnancy.

If you plan to stop this medication, your healthcare provider might suggest that you slowly lower the dose instead of stopping all at once. Some people might have a return of their symptoms (relapse) if they stop this medication during pregnancy. If you stop taking this medication, it is important to have other forms of support in place (e.g. counseling or therapy) and a plan to restart the medication after delivery, if needed. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

For more information about depression or anxiety, please see our fact sheets at https://mothertobaby.org/fact-sheets/depression-pregnancy/ or at https://mothertobaby.org/fact-sheets/anxiety-fact/.

I take fluoxetine. Can it make it harder for me to get pregnant?

Fluoxetine has been studied in women having medical treatments because they were already having a hard time getting pregnant. In these studies, those who took fluoxetine got pregnant at the same rate as those who did not take fluoxetine.

Does taking fluoxetine increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. A small number of studies did not find a greater chance of miscarriage when fluoxetine was used in pregnancy.

Does taking fluoxetine increase the chance of birth defects?

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 an exposure, like fluoxetine, might increase the chance of birth defects in a pregnancy. Fluoxetine use is not expected to increase the chance of birth defects. There are reports of over 10,000 pregnancies exposed to fluoxetine in the first trimester (when many major birth defects can happen). No pattern of birth defects has been found and most studies have not found an increased chance of birth defects related to fluoxetine use.

Some studies have suggested an increased chance of heart defects or other birth defects. However, there is no proven increased chance of birth defects directly related to fluoxetine.

Does taking fluoxetine in pregnancy increase the chance of other pregnancy-related problems?

Some studies suggest a higher chance of preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth) with the use of fluoxetine in pregnancy. However, research has also shown that when conditions such as depression or anxiety are untreated or undertreated during pregnancy, there could be an increased chance of pregnancy complications. This makes it hard to know if it is the medication, the underlying condition, or other factors that might increase the chance for these problems.

Some, but not all, studies have suggested that when women who are pregnant take SSRIs during the second half of pregnancy, their babies might have an increased chance for a serious lung condition called persistent pulmonary



hypertension (PPH). PPH happens in 1 or 2 out of 1,000 births. A recent report that combined results from several studies suggested the chance for PPH might be increased if an SSRI was used during pregnancy. However, it was not clear if this was due to medication exposure or to other exposures that people who take SSRIs have in common, such as higher rates of smoking. Data from studies suggest the overall chance for PPH when an SSRI is used in pregnancy is less than 1/100 (less than 1%).

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

The use of fluoxetine during pregnancy and/or in the third trimester can cause temporary symptoms in newborns soon after birth. These symptoms are sometimes referred to as withdrawal. Symptoms include being irritable and/or jittery, crying, tight muscles, trouble breathing, unusual sleep patterns, tremors (shivers), and/or trouble eating. In most cases symptoms are mild and go away in a few weeks with no treatment, or with only supportive care. Not all babies exposed to fluoxetine will have these symptoms. There might be a higher chance for withdrawal symptoms if other psychiatric medications are also taken with fluoxetine during pregnancy. It is important that your healthcare providers know you are taking fluoxetine so that if symptoms occur your baby can get the care that is best for them.

Does taking fluoxetine in pregnancy affect future behavior or learning for the child?

A few studies have looked at the development of children from age 16 months to 7 years and did not find differences between children who were exposed to fluoxetine during pregnancy and those who were not. Most studies found no increase in attention deficit hyperactivity disorder (ADHD) in children exposed to SSRIs like fluoxetine during pregnancy. Most studies also find that SSRIs like fluoxetine do not appear to increase the chance of autism spectrum disorders (ASD) after adjusting for factors such as maternal illness.

Breastfeeding while taking fluoxetine:

Fluoxetine gets into breastmilk and most reports find no side effects in breastfed babies. In a small number of cases, irritability, vomiting, diarrhea, and less sleep have been reported. One study noted slightly less weight gain in infants exposed to fluoxetine via breast milk; however, this would likely only be an issue if the infant's weight gain was already a concern. One study showed that mental and physical development was normal for infants exposed to fluoxetine in breastmilk in their first year of life. If you suspect the baby has any symptoms (such as irritability, vomiting, diarrhea, trouble sleeping, or trouble gaining weight) contact the child's healthcare provider.

The product label for fluoxetine recommends women who are breastfeeding not use this medication. But the benefit of treating your condition might outweigh possible risks. Your healthcare providers can talk with you about using fluoxetine and what treatment is best for you. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes fluoxetine, could it affect fertility or increase the chance of birth defects?

Fluoxetine and other SSRIs have been reported to cause some sexual side effects, such as lower sexual desire or problems with ejaculation. This can affect a man's fertility (ability to get a woman pregnant). Studies looking at fluoxetine in a small number of men have reported that sperm quality can be affected (but still within the normal range) with long-term fluoxetine use. The sperm quality improved when fluoxetine was stopped. In general, exposures that men have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at http://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Please click here for references.



Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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