Fluoxetine (Prozac®)

This sheet is about exposure to fluoxetine in pregnancy and while breastfeeding. This information is based on published 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). It 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 a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs). 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/.

Sometimes when women find out they are pregnant, they think about changing how they take their medication or stopping it altogether. However, it is important to talk with your healthcare providers before making any changes to how you take your medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

If you plan to stop taking this medication, your healthcare provider might suggest slowly lowering the dose instead of stopping it all at once. Some might have a return of their symptoms (relapse) if they stop taking this medication during pregnancy. If you stop taking this medication, it is important to have other forms of support in place, such as counseling or therapy, and a plan to restart the medication after delivery, if needed. Stopping this medication suddenly can cause withdrawal symptoms. It is not known if or how withdrawal might affect pregnancy.

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

Fluoxetine has been studied in women receiving medical treatment for trouble getting pregnant. In these studies, women who took fluoxetine became pregnant at the same rate as women 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.

Some studies have suggested an increased chance of heart defects or other birth defects with fluoxetine use. However, most studies have not found an increased chance of birth defects with fluoxetine use, and there is no proven increased chance of birth defects directly related to fluoxetine.

There are reports of more than 10,000 pregnancies exposed to fluoxetine during the first trimester, when many major birth defects can happen. No pattern of birth defects has been found. Overall, fluoxetine use is not expected to increase the chance of birth defects.

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 of pregnancy) or low birth weight (weighing less than 5 pounds, 8 ounces [2,500 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, underlying conditions, or other factors that might increase the chance of these problems.

Some studies have suggested that taking SSRIs during the second half of pregnancy might increase the chance of a

serious lung condition called persistent pulmonary hypertension (PPH) in newborns. PPH occurs in about 1 or 2 out of 1,000 births. A recent report combining the results of several studies suggested that the chance of PPH might be higher with SSRI use during pregnancy. However, it is not clear if this is due to the medication or other factors that are more common among women who take SSRIs, such as smoking. Overall, the chance of PPH when an SSRI is used during 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 of 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 child development from 16 months to 7 years of age and found no differences between children exposed to fluoxetine during pregnancy and those who were not. Most studies have not found an increased chance of attention-deficit/hyperactivity disorder (ADHD) in children exposed to SSRIs, such as fluoxetine, during pregnancy. Most studies also have not found an increased chance of autism spectrum disorder (ASD) after considering other factors, such as the mother's 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.

Some older product labels for fluoxetine recommend that women who are breastfeeding not use this medication. More recent product labels do not include this recommendation. The benefit of treating your condition might outweigh possible risks of untreated illness. 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 can cause sexual side effects, such as lower sexual desire or problems with ejaculation. These effects can affect male fertility (the ability to make healthy sperm). Studies in a small number of men have found that long-term fluoxetine use may affect sperm quality, although it remained within the normal range. Sperm quality improved after fluoxetine was stopped. In general, exposures that men have are less likely 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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