



ORGANIZATION
OF TERATOLOGY
INFORMATION
SERVICES

For more information regarding OTIS or a Teratology Information Service in your area, call OTIS Information at (866) 626-6847 or visit us online at www.OTISpregnancy.org.

Paxil (paroxetine) and Pregnancy

This information will help you determine if your prenatal exposure to Paxil represents an increased fetal risk. With every pregnancy, all women have a 3 to 5 percent chance to have a baby with a birth defect.

What is Paxil?

Paxil is a medication used to treat depression, social anxiety disorder, obsessive compulsive disorder, and panic disorder. Paxil belongs to the class of antidepressants known as selective serotonin reuptake inhibitors or SSRIs. The generic name for Paxil is paroxetine.

I am taking Paxil, but I would like to stop taking it before becoming pregnant. How long does Paxil 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 Paxil to be gone from the body after taking the last dose. There are case reports of people who have had withdrawal symptoms when suddenly stopping use of Paxil. It may be preferable to gradually reduce the dosage before quitting completely. The benefits of taking the medication for your specific situation, and any possible adverse outcomes from not taking it, or any potential risks to the baby if you find out you are already pregnant, should be discussed with your health care provider before you decide to stop taking Paxil.

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

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

I have heard that taking Paxil can cause a miscarriage. Is this true?

We do not know for sure if there is any increased risk for miscarriage with the use of Paxil early in pregnancy.

Can taking Paxil during my pregnancy cause birth defects?

The available data suggests that the use of Paxil during pregnancy is unlikely to significantly increase the risk for birth defects over that of the general population. Studies have looked at over 200 pregnancies during which the mothers took Paxil, both during the first trimester and later in pregnancy, and all resulted in the births of apparently normal infants.

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

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

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

The use of SSRIs may affect blood clotting. There have been several reports of abnormal bleeding in individuals beginning Paxil treatment. Presently there are no reports of abnormal bleeding in women or the babies of women who were treated with Paxil during pregnancy. There have also been some studies that have suggested that exposure to Paxil may increase the risk for premature delivery. Further study is needed before it can be determined if these risks exist.

I need to take Paxil throughout my entire pregnancy. Will it cause any adverse effects in my baby at birth?

If you are taking Paxil at the time of delivery, your baby may experience some complications requiring extra care. Symptoms of withdrawal such as problems breathing, jitteriness, increased muscle tone, irritability, sleepiness, tremors and difficulty eating may occur. One study has also noted an increase in the risk of low blood sugar and jaundice in the newborn. You should inform your obstetrician and your baby's pediatrician that you are taking Paxil so that any extra care can be readily provided.

Can I take Paxil while breastfeeding?

Studies have shown that one to two percent of the amount of Paxil that the mother takes passes into the breast milk. There is one case report and two small studies regarding the use of Paxil during breastfeeding. The reports found no adverse effects. The authors of one study recommend taking Paxil in the evening if the infant is not fed at night to decrease infant exposure. Long term studies on infants exposed to Paxil in breast milk have not been conducted. Please talk to your pediatrician if you need to take Paxil while breastfeeding.

**September 2002.
Copyright OTIS.
Reproduced by permission.**



ORGANIZATION
OF TERATOLOGY
INFORMATION
SERVICES

REFERENCES:

- Baldwin, J.A., *et al.* The reproductive toxicology of paroxetine. *Acta Psychiatr. Scand* 80 (suppl. 350): 37-39, 1989.
- Begg, E.J., *et al.* Paroxetine in human milk. *Br J Clin Pharmacol* 48: 142-14.
- Bloch, M., *et al.* Severe psychiatric symptoms associated with paroxetine withdrawal. *Lancet* 346 (8966): 57, 1995.
- Briggs, G.G., Freeman, R.K., and Yaffe, S.J. Drugs in Pregnancy and Lactation. Fifth Edition. Williams & Wilkins, Baltimore MD. 1998.
- Cooper, T.A., *et al.* Spontaneous ecchymoses due to paroxetine administration. *Am J Med* 104: 197-198, 1998.
- Costei, A., *et al.* Perinatal Outcome Following Third Trimester Exposure to Paroxetine. Abstract: Presented at Platform Session May 6, 2002, Baltimore, MD.
- Dahl, M.L., Olhager, E. and Ahlner, J. Paroxetine withdrawal syndrome in a neonate. *Br J Psychiatry* 171: 391-392, 1997.
- Grush, L. Risk of fetal anomalies with exposure to selective serotonin reuptake inhibitors. *JAMA* 279 (23): 1873, 1998.
- Kulin, N.S., *et al.* Pregnancy outcome following maternal use of the new selective serotonin reuptake inhibitors: a prospective controlled multicenter study. *JAMA* 279 (8): 609-610, 1998.
- Lamberg, L. Safety of antidepressant use in pregnant and nursing women. *JAMA* 282 (3): 222-223.
- McElhatton, P.R., *et al.* The outcome of pregnancy in 689 women exposed to therapeutic doses of antidepressants. A collaborative study of the European Network of Teratology Information Services (ENTIS). *Reproductive Toxicology* 10 (4): 285-294, 1996.
- Nijhuis IJM., *et al.* Withdrawal reactions of a premature neonate after maternal use of paroxetine. *Arch Dis Child Fetal Neonatal Ed* 84(1):F77, 2001.
- Nulman, I., *et al.* Neurodevelopment of children exposed in utero to antidepressant drugs. *NEJM* 336 (4): 258-262, 1996.
- Ohman, R., *et al.* Excretion of paroxetine into breast milk. *J Clin Psychiatry* 60 (8): 519-523, 1999.
- Spigset, O., *et al.* Paroxetine level in breast milk. *J Clin Psychiatry* 57 (1): 39, 1996.
- SmithKline Beecham Pharmaceuticals, Prescribing Information, 1999.