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Pseudoephedrine, Phenylephrine and Pregnancy

This sheet talks about the risks that exposure to pseudoephedrine or phenylephrine can have during pregnancy. With each pregnancy, all women have a 3% to 5% chance of having a baby with a birth defect. This information should not take the place of medical care and advice from your health care provider.

What are pseudoephedrine and phenylephrine?

Pseudoephedrine and phenylephrine are oral decongestants that are frequently used to treat nasal congestion (stuffy nose) caused by colds or allergies. Pseudoephedrine is sold in pharmacies under brand names such as Sudafed[®], Drixoral Nasal Decongestant[®] and Myfedrine[®]. Pseudoephedrine can also be found in combination products for the treatment of cold and allergy symptoms. In many places, products containing pseudoephedrine have been taken off the shelves and are instead available upon request behind the pharmacy counter. Phenylephrine has replaced pseudoephedrine in many cold preparations that are available on the shelves.

Can using pseudoephedrine or phenylephrine increase the risk of miscarriage or make it more difficult for me to become pregnant?

There are no studies looking at whether these decongestants could have an effect on fertility or increase the risk of pregnancy loss.

I just found out that I am pregnant and I took some pseudoephedrine for a cold that I had early in my pregnancy. Could this cause a birth defect in my baby?

Probably not. Four studies involving about 2000 women exposed to pseudoephedrine in the first trimester did not find an increased risk for birth defects.

There have been some studies that found that the use of pseudoephedrine during the first trimester was related to an increase in the risk of gastroschisis, which is an opening in the baby's abdominal wall. Based on these studies, the chance that you could have a child with gastroschisis because you took pseudoephedrine is very small, with only 2 to 6 cases for every 10,000 births (less than one tenth of one percent).

Some studies have suggested that medications including pseudoephedrine that are used to treat the symptoms of a cold, fever, or flu, might slightly

increase the risk for various birth defects. Gastroschisis and these other birth defects could result from constriction (narrowing) of blood vessels. Pseudoephedrine constricts blood vessels so it is possible that there is a connection. However, the design of these studies does not allow any definite conclusions to be made.

When possible, pseudoephedrine should be avoided during the first trimester of pregnancy. However, if you have already used pseudoephedrine in the first trimester, the risk of birth defects for the developing baby, if any, is very small.

Is it true that smoking can increase the risk of birth defects related to the use of pseudoephedrine?

Possibly. Pseudoephedrine use and cigarette smoking can both constrict blood vessels. A study showed that when a mother who smokes cigarettes also takes pseudoephedrine, the risk of having a child with gastroschisis may be greater than if she was exposed to either one alone. The risk remains very low, however.

Does using phenylephrine in the first trimester cause birth defects?

Probably not. Two studies involving more than 1500 women who took phenylephrine in the first trimester did not show significantly increased risks for birth defects. Like pseudoephedrine, phenylephrine constricts blood vessels. However, studies have not looked at whether phenylephrine use is possibly associated with birth defects like gastroschisis.

I am 8 months pregnant and for the past few days I have been suffering from a cold. Can I use pseudoephedrine or phenylephrine to relieve my nasal congestion?

For pregnant women suffering from nasal congestion, alternatives to an oral medication may be helpful. For instance, saline solutions such as Salinex[®] can be sprayed into the nostrils as needed. If this does not provide enough relief, a local decongestant nasal

spray may be used. Your doctor can suggest other nasal sprays that may be effective. As the body absorbs only a small amount of these products, they pose little or no risk to the fetus. Use of nasal sprays may be limited (not more than 3 to 5 days of use in a row) to prevent rebound congestion.

After the first trimester, pseudoephedrine or phenylephrine can be used for a few days until the congestion goes away. If you need a decongestant, it is best to choose a preparation that contains only pseudoephedrine or phenylephrine. This avoids exposing the developing baby to other medications that may not be needed. In addition, the recommended dose should not be exceeded.

Because both pseudoephedrine and phenylephrine constrict blood vessels, you should not use them if you have high blood pressure. Pseudoephedrine may be preferable to phenylephrine for use during the second or third trimester because it may have less effect on blood pressure and may treat congestion better than phenylephrine. Your doctor or pharmacist can help you choose the medication that is best for you.

Can I use pseudoephedrine or phenylephrine if I am breastfeeding?

At recommended doses, only a small amount of pseudoephedrine gets into breast milk. In general, pseudoephedrine does not cause any side effects in the breastfed baby, but a few cases of irritability have been reported.

One study suggested that taking pseudoephedrine may reduce the amount of milk that you produce. Given this concern, if you are breastfeeding you may want to first try a saline solution or a local decongestant to relieve nasal congestion. If these products do not help, pseudoephedrine can be used once breastfeeding is well established. If you notice a decrease in your milk supply, pseudoephedrine use should be stopped.

There are no studies looking at the use of phenylephrine in breastfeeding mothers. Studies in animals have shown that like pseudoephedrine, phenylephrine may reduce milk supply. Because there is little information about the safety of phenylephrine while breastfeeding, use of nasal sprays or short term use of pseudoephedrine may be preferred.

What if the father of the baby takes pseudoephedrine or phenylephrine?

There are no studies looking at possible risks to a pregnancy when a father takes pseudoephedrine or phenylephrine, but a father's use of these common decongestants is not expected to cause birth defects. In general, exposure of the father is unlikely to increase the risk to a pregnancy, because, unlike the mother, the father does not share a blood connection with the

developing baby. For more information, please see the OTIS fact sheet about Paternal Exposures at <http://otispregnancy.org/pdf/paternal.pdf>.

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References:

- Aljazaf K, et al. 2003. Pseudoephedrine: effects on milk production in women and estimation of infant exposure via breastmilk. *Br J Clin Pharmacol* 56(1):18-24.
- Anastasio GD, et al. 1992. Fetal tachycardia associated with maternal use of pseudoephedrine, an over-the-counter oral decongestant. *J Am Board Fam Pract* 5(5):527-8.
- Aselton P, et al. 1985. First-trimester drug use and congenital disorders. *Obstet Gynecol* 65(4):451-455.
- Briggs GG. 2002. Drug effects on the fetus and breast-fed infant. *Clin Obstet Gynecol* 45(1):6-21.
- Bruckmaier R, et al. 1991. Effects of alpha- and beta-adrenergic agonists in intramammary pressure and milk flow in dairy cows. *J Dairy Res* 58:411-419.
- Findlay JW, et al. 1984. Pseudoephedrine and triprolidine in plasma and breast milk of nursing mothers. *Br J Clin Pharmacol* 18(6):901-906.
- Hale, TW. 2006. *Medications and Mothers' Milk*. Twelfth Edition. Amarillo, TX: Pharmasoft Medical Publishing.
- Heinonen OP, et al. 1977. *Birth Defects and Drugs in Pregnancy*. Littleton, MA: John Wright-PSG.
- Ito S, et al. 1993. Prospective follow-up of adverse reactions in breast-fed infants exposed to maternal medication. *Am J Obstet Gynecol* 168(5):1393-1399.
- Jick H, et al. 1981. First-trimester drug use and congenital disorders. *JAMA* 246(4):343-346.
- Miller RK. 1992. From the pages of Teratology: vitamin A to pseudoephedrine issues in patient counselling. *Teratology* 45(4):341-343.
- Rosa F. 1993. Personal communication. Cited in: Briggs GG, et al. 2005. *Drugs in Pregnancy and Lactation: A Reference Guide to Fetal and Neonatal Risk*. Seventh Edition. Baltimore, MD: Williams & Wilkins.
- Schatz M, et al. 1997. Asthma and allergy in pregnancy. *Clin Perinatol* 24(2):407-432.
- Smith J, et al. 1994. Drugs of choice for pregnant women. In: Koren G. *Maternal-fetal Toxicology. A Clinician's Guide*. 1994. Second Edition. New York NY: Marcel Dekker Inc.
- Torfs CP, et al. 1996. Maternal medications and environmental exposures as risk factors for gastroschisis. *Teratology* 54(2):84-92.
- Werler MM, et al. 2003. Association of vasoconstrictive exposures with risks of gastroschisis and small intestinal atresia. *Epidemiology* 14(3):349-54.
- Werler MM, et al. 1992. First trimester maternal medication use in relation to gastroschisis. *Teratology* 45(4):361-367.
- Werler MM, et al. 2002. Maternal medication use and risks of gastroschisis and small intestinal atresia. *Am J Epidemiol* 155(1):26-31.
- Werler MM, et al. 2004. Vasoactive exposures, vascular events, and hemifacial microsomia. *Birth Defects Res A Clin Mol Teratol* 70(6):389-395.

*If you have questions about the information on this fact sheet or other exposures during pregnancy, call **OTIS** at 1-866-626-6847.*