

Fact Sheet

by the Organization of Teratology Information Specialists (OTIS)

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Fexofenadine

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 fexofenadine 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 fexofenadine?

Fexofenadine is an over-the- counter antihistamine. Antihistamines are used to lessen the symptoms of allergic reactions and colds, including sneezing, runny nose, watery eyes and itchy throat. Fexofenadine has been sold under brand names that include Allegra®.

The medicine terfenadine changes into fexofenadine in the body, so information on terfenadine may also be helpful for predicting the effects of fexofenadine on pregnancy and breastfeeding.

I just found out I am pregnant. Should I stop taking fexofenadine?

You should always talk with your healthcare provider before making any changes in your medications. It is important to consider the benefits of treating allergy symptoms and other conditions during pregnancy. Treating allergy symptoms may reduce asthma symptoms and the need for additional asthma medicines.

In people who took 60 mg of fexofenadine twice a day, it could take up to 4 days for all of this medication to leave the body.

Can fexofenadine cause a miscarriage?

There are no studies that have looked at whether fexofenadine can increase the chance for a miscarriage.

I am pregnant. Can use of fexofenadine during pregnancy cause birth defects?

So far, studies on both fexofenadine and terfenadine have not found an increase in birth defects with use of these medicines.

Can use of fexofenadine cause other pregnancy complications?

No studies have looked at whether fexofenadine could cause other pregnancy complications. A study on terfenadine found no increase in premature delivery or low birth weight with use during pregnancy.

Can I breastfeed while taking fexofenadine?

Fexofenadine is less likely to cause sleepiness in adults than some other antihistamines. For this reason, fexofenadine may be preferred for breastfeeding over antihistamines that do cause sleepiness. Information from terfenadine suggests that the amount of fexofenadine in the breastmilk is small. One study estimated that a baby that was breastfed by a mother taking fexofenadine got less than 1% of the mother's dose. This dose would be too low to cause problems for the baby.

When 25 women were asked by telephone how their babies were doing while they were taking terfenadine and breastfeeding, three mothers said their babies experienced irritability but that they did not need to take the babies to a healthcare provider. It is not possible to know if their irritability was caused by terfenadine in breastmilk.

It is possible, but not proven, that antihistamines may lower the amount of milk a woman makes. This might be more likely to occur if antihistamines are used in combination with an oral decongestant like pseudoephedrine or phenylephrine, or if used before beginning to breastfeed.

Be sure to talk to your health care provider about all your breastfeeding questions.

What if the father of the baby takes fexofenadine?

There is no evidence that suggests that a man's fexofenadine use would cause any problems during his partner's pregnancy. 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 https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/.

Selected References

- Craig-McFeely PM, Acharya NV, Shakir SAW: 2001. Evaluation of the safety of fexofenadine from experience gained in general practice use in England in 1997. Eur J Clin Pharmacol 57(4):313-320.
- Diav-Citrin O, et al. 2003. Pregnancy outcome after gestational exposure to loratedine or antihistamines: a prospective controlled cohort study. J Allergy Clin Immunol 111(6):1239-1243.
- Gilboa SM, et al. 2009. National Birth Defects Prevention Study: Use of antihistamine medications during early pregnancy and isolated major malformations. Birth Defects Res A Clin Mol Teratol 85(2):137-150.
- Ito S, et al. 1993. Prospective follow-up of adverse reactions in breast-fed infants exposed to maternal medication. Am J Obstet Gynecol. 168:1393-9.
- Kallen B. 2002. Use of antihistamine drugs in early pregnancy and delivery outcome. J Matern Fetal Neonatal Med 11:146-152.
- Loebstein R, et al. 2000. Pregnancy outcome after gestational exposure to terfenadine: A multicenter, prospective controlled study. Immunology and Allergy Clinics of North America 20(4):807-30.
- Lucas BD Jr, et al: 1995. Terfenadine pharmacokinetics in breast milk in lactating women. Clin Pharmacol Ther. Apr;57(4):398-402.
- Schatz M, Petitti D. 1997. Antihistamines and pregnancy. Ann Allergy Asthma Immunol 78:157-159.

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