



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Montelukast (Singulair®)

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 montelukast 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 montelukast?

Montelukast (Singulair®) is an asthma and allergy medication that is taken by mouth. Montelukast works by blocking a group of chemicals in the body called leukotrienes. Leukotrienes cause inflammation (swelling) of the airways, which can make it difficult to breathe. Montelukast is used to help control allergy symptoms and to make an asthma attack less likely. It is not used to stop an asthma attack.

I have been taking montelukast and just found out I am pregnant. Should I stop?

You should always speak with your health care provider before making any changes in your medication. Montelukast has been less studied during pregnancy than some other asthma medications. However, if you have had a good response with montelukast controlling your asthma before pregnancy, it may be appropriate to continue using it in pregnancy.

It is important to think about the benefits of controlling asthma symptoms during pregnancy. Untreated asthma increases the chance for complications for both the baby and the mother. For more information on asthma in pregnancy, please see the MotherToBaby fact sheet [Asthma and Pregnancy](https://mothertobaby.org/fact-sheets/asthma-and-pregnancy/) at <https://mothertobaby.org/fact-sheets/asthma-and-pregnancy/>.

Can taking montelukast during pregnancy cause a birth defect?

Current information does not suggest an increased chance for a pattern of birth defects when montelukast is taken during pregnancy. The manufacturer of montelukast reported a possible association with limb defects (problems with fingers, toes, arms or legs). However, only a few cases of limb defects were reported. The types of limb defects were very different from one another, which suggest they do not have a common cause such as an exposure to a particular medication. Also, the mothers of these children were taking other medications during their pregnancies. A medical record review of 1535 women who reported use of montelukast in pregnancy did not find any cases of limb defects. In addition, there have been two studies including 276 women that have not supported an increased chance for birth defects with first trimester use.

Can taking montelukast during pregnancy cause other pregnancy complications?

A few studies have reported a decrease in infant birth weight when the mother used montelukast during pregnancy. However, this decrease may be due to more severe or poorly controlled asthma and not the montelukast itself. The women in these studies who needed montelukast often had severe asthma and sometimes needed more than one medication. One study did not notice a difference in birth weight of babies whose mothers used montelukast when compared to babies whose mothers used other asthma treatments. More studies are needed to confirm the cause of the low birth weight sometimes seen in babies of women with asthma.

Is it safe for me to take montelukast while I am breastfeeding?

There are no studies looking at montelukast and breastfeeding. Montelukast is thought to pass into breast milk. Montelukast is used in infants as young as 6 months of age without side effects; thus, the risk to a nursing baby is likely

to be low. Be sure to talk to your health care provider about all your choices for breastfeeding.

Is there a concern if my partner was taking montelukast when I got pregnant?

There are no studies looking at paternal use of montelukast prior to or at the time of conception. 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/>.

MotherToBaby is currently conducting a study looking at asthma and the medications used to treat asthma in pregnancy. If you are interested in taking part in this study, please call 1-877-311-8972.

Selected References:

- Aharon, D. 1998. Pharmacology of Leukotriene receptor antagonist. American Journal of Respirator Critical Care Medicine. 157; 214-219
- Bakhireva, LN et al. 2007. Safety of leukotriene receptor antagonists in pregnancy. Journal of Allergy and Clinical Immunology, 119; 618-625
- Merck Research Laboratories: Fourteenth Annual Report on exposures during pregnancy from the Merck Pregnancy Registry for SINGULAIR (montelukast sodium) covering the period from U.S. approval (February 20,1998) through July 3, 2012. Merck Research Labs, West Point, PA. www.merckpregnancyregistries.com
- Nelsen LM et al. 2012. Congenital malformations among infants born to women receiving montelukast, inhaled corticosteroids, and other asthma medications. J Allergy Clin Immunol. 129(1):251-4.e1-6.
- Sarkar M, et al. 2009. Montelukast use during pregnancy: a multicentre, prospective, comparative study of infant outcomes Eur J Clin Pharmacol.

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