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Montelukast (Singulair[®]) and Pregnancy

This sheet talks about the risks that exposure to montelukast 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 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 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?

No. You should not stop taking any medication without first talking to your health care provider. 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 prior to pregnancy, it may be appropriate to continue using it in pregnancy.

It is important to consider the benefits of controlling asthma symptoms during pregnancy. Untreated asthma increases the risk for complications for both the baby and the mother. For more information on asthma in pregnancy, please see the OTIS fact sheet [Asthma and Pregnancy](#).

Can taking montelukast during pregnancy cause a birth defect?

Current information does not suggest an increased risk for a birth defect 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 risk for birth defects with first trimester use.

The drug manufacturer is following women who have taken montelukast during pregnancy. To enroll, call (800) 986-8999.

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 the result of more severe or poorly controlled asthma rather than the montelukast itself. The women in these studies who needed montelukast often had severe

asthma and sometimes needed more than one medication. Further studies are needed to confirm the cause of the low birth weight sometimes seen in babies of women with asthma.

A recent study of montelukast in pregnancy found that babies of mothers who continued their medication until the end of pregnancy had better outcomes in the newborn period, compared to the babies of mothers who stopped taking montelukast earlier in pregnancy.

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

There are no studies looking at montelukast and breastfeeding. Montelukast is expected 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.

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, medications that the father takes do not increase risk to a pregnancy because the father does not share a blood connection with the developing baby. For more information, please see the OTIS fact sheet [Paternal Exposures and Pregnancy](#).

OTIS 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.

August 2010.
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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: Eleventh 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 31, 2009. Merck Research Labs, West Point, PA. www.merckpregnancyregistries.com

Sarkar M, et al. Montelukast use during pregnancy: a multicentre, prospective, comparative study of infant outcomes Eur J Clin Pharmacol. 2009 Aug 26.

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