Montelukast (Singulair®) and Pregnancy

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 professional.

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?

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 risk for complications for both the baby and the mother. For more information on asthma in pregnancy, please see the OTIS fact sheet at http://www.mothertobaby.org/files/asthma.pdf.

Can taking montelukast during pregnancy cause a birth defect?

Current information does not suggest an increased risk 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 risk 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 the 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. More 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 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 discuss any concerns and all your choices for breastfeeding with your health care provider.

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. For more information, please see the OTIS fact sheet on Paternal Exposures at http://www.mothertobaby.org/files/paternal.pdf

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.

Selected References:


Bakhireva, LN et al. 2007. Safety of leukotriene receptor antagonists in pregnancy. Journal of Allergy and Clinical Immunology, 119; 618-625

