



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 take montelukast. Can it make it harder for me to get pregnant?

It is unknown. No studies have been done to see if montelukast could make it harder for a woman to get pregnant.

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

Speak with your healthcare providers before making changes in using this medication. Montelukast has been less studied during pregnancy than some other asthma medications. However, if montelukast helped control 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 on asthma at <https://mothertobaby.org/fact-sheets/asthma-and-pregnancy/pdf/>.

Does taking montelukast increase the chance for miscarriage?

It is unknown. No studies have been done to see if montelukast increases the chance for miscarriage.

Can taking montelukast during pregnancy cause a birth defect?

Current information does not suggest an increased chance for 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 in the report were 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. Medical record reviews of thousands of women who reported use of montelukast in pregnancy did not find any cases of limb defects or other birth 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 chance for some pregnancy complications when the mother used montelukast during pregnancy, such as: lower birth weight, premature delivery (born before week 37), and preeclampsia (a pregnancy-related disorder that can cause high blood pressure and protein in the urine). However, these could also 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.

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

Montelukast is thought to pass into breast milk at very low levels. One study found that nursing infants would likely receive less than 1% of the mother's dose through breastmilk, and would be lower than the dose used to treat an infant. 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. There are no studies looking at effects in newborns who are breastfeeding while their mothers use montelukast. Talk with your healthcare provider about your breastfeeding questions.

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 at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

MotherToBaby is currently conducting a study looking at asthma and the medications used to treat asthma in pregnancy. If you are interested in learning more, please call 1-877-311-8972 or visit <https://mothertobaby.org/join-study>.

Selected References:

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