Montelukast (Singulair®)

This sheet is about exposure to montelukast in pregnancy and while breastfeeding. This information is based on published research studies. It should not take the place of medical care and advice from your healthcare provider.

What is montelukast?

Montelukast is a medication that has been used to treat asthma and allergies. While montelukast has been used to lower the chance of having an asthma attack, it does not stop an asthma attack. Montelukast is sold under the brand name Singulair®.

Sometimes when women find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take your medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

Asthma that is not well-treated can increase the chance of complications for the pregnant woman as well as the pregnancy. For more information, please see the MotherToBaby fact sheet on asthma at https://mothertobaby.org/fact-sheets/asthma-and-pregnancy/.

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

Studies have not been done in humans to see if montelukast can make it harder to get pregnant. Animal studies showed no effect on fertility (ability to get pregnant).

Does taking montelukast increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Several studies have not found an increased chance of miscarriage with the use of montelukast during pregnancy.

Does taking montelukast increase the chance of birth defects?

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at research studies to try to understand if an exposure, like montelukast, might increase the chance of birth defects in a pregnancy.

Most available information suggests that the use of montelukast in pregnancy does not increase the chance of birth defects above the background risk. Medical record reviews of thousands of pregnancies exposed to montelukast have not found an increased risk of birth defects. Smaller studies, including those with over 200 exposed pregnancies, have also not suggested a higher risk.

Does taking montelukast in pregnancy increase the chance of other pregnancy-related problems?

A few studies have reported an increased chance of some pregnancy complications when montelukast was used during pregnancy, such as lower birth weight, preterm delivery (delivery before week 37), and preeclampsia (high blood pressure and problems with organs, such as the kidneys), which can lead to seizures (called eclampsia). However, the women in these studies often had severe asthma and sometimes were taking more than one medication. It is not clear if the reported complications are due to montelukast, the condition being treated, or other factors. Other studies have not found an increased chance of preterm delivery or low birth weight (weighing less than 5 pounds, 8 ounces [2,500 grams] at birth).

Does taking montelukast in pregnancy affect future behavior or learning for the child?

It is not known if taking montelukast in pregnancy can increase the chance of behavior or learning issues in children. One study looking at the class of medications that montelukast belongs to (leukotriene-receptor antagonists) did not find an increased chance of attention-deficit/hyperactivity disorder (ADHD), autism spectrum disorder (ASD), or Tourette syndrome in children exposed during pregnancy.

Breastfeeding while taking montelukast:

Montelukast gets into breast milk in small amounts. One study found that breastfed infants are likely to receive a smaller amount of the medication through breast milk than the dose used to treat infants directly. Side effects are unlikely, and no special safety measures are required when using montelukast while breastfeeding. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes montelukast, could it affect his fertility or increase the chance of birth defects?

Studies have not been done in humans to see if montelukast could affect men's fertility (ability to make healthy sperm) or increase the chance of birth defects. Animal studies showed no effect on fertility. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet on Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Help us find answers to common questions!

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.

Please click here for references.

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