Montelukast (Singulair®)

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

What is montelukast?
Montelukast is 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 people 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 person who is pregnant 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. It is not known if montelukast can increase the chance of miscarriage. One study did not show an increase in the rate of miscarriage with use of montelukast during pregnancy.

Does taking montelukast increase the chance of birth defects?
Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. 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 reportedly exposed to montelukast did not find an increased chance of birth defects. Other studies looking at a combined total of over 200 pregnancies exposed to montelukast have not suggested an increased chance of birth defects.

Does taking montelukast in pregnancy increase the chance of other pregnancy-related problems?
A few studies have reported a chance for 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 people in these studies who needed montelukast often had severe asthma and sometimes needed more than one medication. It is not clear if the reported complications are due to montelukast, the condition being treated, or other factors. One study did not report a difference in the birth weight of babies exposed to montelukast when compared to babies exposed to other asthma treatments.

Does taking montelukast in pregnancy affect future behavior or learning for the child?
Studies have not been done to see if montelukast can increase the chance of behavior or learning issues for the child.

Breastfeeding while taking montelukast:
Montelukast gets into breastmilk in small amounts. One study found that nursing infants would likely receive less of the medication in breastmilk than the dose used to treat an infant directly. Usually, no special precautions are required when using montelukast while breastfeeding. Be sure to talk to your healthcare provider about all your breastfeeding questions.
If a male takes montelukast, could it affect fertility or increase the chance of birth defects?

Studies have not been done in humans to see if montelukast could affect male fertility (ability to get partner pregnant) or increase the chance of birth defects above the background risk. Animal studies showed no effects 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/.

Please click here for references.

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.