

# Montelukast (Singulair®)

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

## ***What is montelukast?***

Montelukast is medication used to treat asthma and allergies. Montelukast works by blocking a group of chemicals in the body called leukotrienes. Leukotrienes cause inflammation (swelling) of the airways, which can make it hard to breathe. Montelukast is used to help control allergy symptoms and to lower the chance of having an asthma attack. It is not used to 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 this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

It is important to think about the benefits of controlling asthma symptoms during pregnancy. Untreated asthma increases the chance for complications for the person who is pregnant as well as the baby. 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.

## ***Does taking montelukast increase the chance for miscarriage?***

Miscarriage can occur in any pregnancy. Based on the studies reviewed, it is not known if montelukast increases the chance for 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.

The manufacturer of montelukast reported a possible link between the use of montelukast during pregnancy and limb defects (problems with fingers, toes, arms or legs). However, only 6 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, these children were exposed to other medications during pregnancy. The label for montelukast notes that the reports did not prove that use of montelukast in pregnancy caused the reported limb defects.

Medical record reviews of thousands of pregnancies reportedly exposed to montelukast did not find an increased chance of limb defects or other birth defects. Other studies looking at a combined total of over 200 pregnancies exposed to montelukast have not suggested an increased chance for birth defects. In summary, based on the studies reviewed, the use of montelukast during pregnancy is not expected to increase the chance of birth defects above the background risk.

## ***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 37 weeks of pregnancy), and preeclampsia (a disorder that can cause high blood pressure and protein in the urine in the person who is pregnant). However, these could also be due to more severe or poorly controlled asthma and not the montelukast itself. 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, more severe or poorly controlled asthma, or other factors. One study did not notice a difference in 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 cause 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 of your breastfeeding questions.

***If a male takes montelukast, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects?***

Studies have not been done to see if montelukast could affect human fertility or increase the chance of birth defects. Animal studies showed no effects on fertility. In general, exposures that fathers or sperm donors have are unlikely to increase the 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/>.

*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.**

**Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at [MotherToBaby.org](https://mothertobaby.org).**

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