

Ustekinumab (Stelara®)

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

What is ustekinumab?

Ustekinumab is a prescription medication used to treat moderate to severe psoriasis, Crohn's disease, and active psoriatic arthritis. Ustekinumab is sold under the brand name Stelara®.

MotherToBaby has fact sheets on psoriasis and psoriatic arthritis <https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/> and Crohn's disease <https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/>.

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.

I am taking ustekinumab, but I would like to stop taking it before becoming pregnant. How long does the drug stay in my body?

People eliminate medication at different rates. On average it takes between 2.5 - 9 months before most of the medication will be gone from the body. It may take longer to clear from the body in some people who have been on ustekinumab for a long period of time.

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

Studies have not been done in humans to see if there is any effect on female fertility.

Does taking ustekinumab increase the chance for miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not been done to see if ustekinumab could increase the chance for miscarriage. One case series report did not find an increased chance for miscarriage among women who took ustekinumab during pregnancy.

Does taking ustekinumab 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. Animal studies have suggested no increase in the chance of birth defects. There are no well-controlled human studies looking at exposure to ustekinumab during pregnancy. There are eight case reports and two small case series that have looked at this question. No increased chance for birth defects was noted in these reports.

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

Large studies have not been done to see if ustekinumab increases the chance for pregnancy-related problems such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth). Case reports have not identified an increased chance for pregnancy complications. More ustekinumab may cross the placenta during the third trimester than in the first trimester.

Can my baby receive live vaccines before one year of age if I take ustekinumab later in pregnancy?

Since ustekinumab may suppress the immune system of the person taking it, there is a theoretical concern that the same thing could happen to the baby if they are exposed during pregnancy. Live vaccines contain a small amount of live virus. If someone has a weakened immune system they may be more likely to develop an infection from the vaccine. Inactivated vaccines do not contain live virus, so they cannot cause the disease they protect against. In the United States, rotavirus is the only live vaccine routinely given in the first year of life. Most people can get inactivated vaccines in the first year of life.

Talk with your child's healthcare provider about your exposure to ustekinumab during pregnancy. They can talk with

you about the vaccines your child should receive and the best time for your child to receive them.

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

Studies have not been done to see if ustekinumab can cause behavior or learning issues for the child.

Breastfeeding while taking ustekinumab:

Ustekinumab has not been well studied during breastfeeding. Because ustekinumab is a very large protein, it is thought that very little medication would pass into breast milk. Ustekinumab is also a medication that is not well absorbed by the GI tract (gut), so any of the medication that gets into breast milk would be unlikely to enter the baby's system. Babies who are born preterm (born before 37 weeks of pregnancy) can have digestive systems that are not fully developed and may be able to absorb more of the medication through breast milk. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

Studies have not been done to see if ustekinumab could affect male fertility or increase the chance of birth defects. 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 Paternal Exposures at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/>.

MotherToBaby is currently conducting a study looking at autoimmune diseases like psoriasis and the medications used to treat autoimmune diseases in pregnancy. If you are interested in taking part in this study, 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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