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. It is given as an infusion into a vein (IV) or as an injection under the skin. 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/].

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.

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

Talk with your healthcare providers before making any changes to how you take your medication. The benefits of taking your medication may outweigh the risks of untreated illness.

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. However, it may take longer to clear from the body in some people who have been on ustekinumab for a long period of time.

Does taking ustekinumab increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. It is not known if ustekinumab increases the chance for miscarriage.

Can taking ustekinumab increase the chance for 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 with at least first trimester exposure to ustekinumab. One pregnancy resulted in a miscarriage; however, this person had other general risk factors for miscarriage. The other pregnancies resulted in healthy infants born at full-term. The maker of ustekinumab also reported on 34 exposures during pregnancy. The chance for birth defects or pregnancy loss was found to be the same as in those who had not taken ustekinumab in pregnancy.

Can I take ustekinumab in the third trimester?

There is very limited information looking at the use of ustekinumab in the third trimester. More ustekinumab may cross the placenta during the third trimester than in the first trimester. However, there are no official recommendations on third trimester use. The decision to use ustekinumab in the later part of pregnancy should be made with your healthcare provider and may be based on your condition and the severity of your symptoms.

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

Since ustekinumab reduces inflammation by acting on your immune system, there is the concern ustekinumab might affect the immune system in an infant who was exposed during pregnancy. Most vaccines given in the first 6 months of life are noninfectious and can be given to a baby even if ustekinumab is present in their blood. Noninfectious vaccines are not live vaccines, meaning a person cannot get the infection from the vaccine.

Live vaccines usually contain a milder form of the virus or bacteria than what you might be exposed to in the community. Live vaccines always carry a small chance a person could get the infection from the vaccine. Live vaccines given in the newborn period are usually avoided, if possible, in the first year of life in case the child’s immune system...
does not respond to the vaccine normally.

Live vaccines include measles-mumps-rubella (MMR), varicella (chicken pox) and rotavirus vaccines. Rotavirus is one of the leading causes of vomiting and severe diarrhea in children. The rotavirus vaccine is the only live vaccine that is routinely recommended for infants less than one year of age in the United States. It is the best way to protect infants against rotavirus.

Always be sure to let your pediatrician know of any medications or exposures during pregnancy and/or breastfeeding. They can discuss the risks and benefits of live vaccines with you.

**Does taking ustekinumab in pregnancy cause long-term problems in behavior or learning for the baby?**

It is not known if ustekinumab can cause behavior or learning issues.

**Can I breastfeed while taking ustekinumab?**

Ustekinumab has not been well studied during breastfeeding. Because ustekinumab is a very large protein, it is likely that very little medicine would pass into breast milk. Ustekinumab is not well absorbed by the 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) 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.

**I take ustekinumab. Can it make it harder for me to get my partner pregnant or increase the chance of birth defects?**

There are no studies looking at possible risks to fertility or a pregnancy when a male takes ustekinumab. 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 ustekinumab and other 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 sign up at https://mothertobaby.org/join-study/.

Please click here for references.