Ustekinumab (Stelara®)

This sheet is about exposure to ustekinumab 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 ustekinumab?

Ustekinumab is a medication that has been used to treat moderate to severe psoriasis, Crohn's disease, and active psoriatic arthritis. The brand name of ustekinumab is 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 your medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

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

Studies have not been done to see if taking ustekinumab can make it harder to get pregnant .

Does taking ustekinumab increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies of over 3000 pregnancies did not find an increased chance of miscarriage when ustekinumab was used during pregnancy.

Does taking ustekinumab 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 ustekinumab, might increase the chance of birth defects in a pregnancy. Studies of over 2,500 pregnancies found no increased chance of birth defects when ustekinumab was used during pregnancy.

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

Studies of over 2000 pregnancies found no increased chance of 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) when ustekinumab was used during pregnancy.

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

Ustekinumab can weaken the immune system of the person taking it, so there's a theoretical (not proven) concern it might also weaken a baby's immune system if they are exposed during pregnancy. Live vaccines, which contain a small amount of live virus, can cause an infection in people with weak immune systems. Inactivated vaccines, which do not contain live virus, cannot cause an infection with the disease they protect from. In the U.S., the rotavirus vaccine is the only live vaccine routinely given in a baby's first year.

Studies of babies exposed to ustekinumab during pregnancy who got the rotavirus vaccine in the first 4 months of life found no higher risk of infections or health problems. There are also reports of babies who were exposed to ustekinumab during pregnancy and received the measles, mumps, and rubella (MMR) vaccine or the varicella vaccine without any health issues.

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?

Four studies of 122 children exposed to ustekinumab during pregnancy showed no increased chance of behavior or learning issues at around 12 months of age.

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. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

A small study of 12 men exposed to ustekinumab reported no effect of on fertility (ability to get a partner pregnant). Larger studies of over 200 men exposed to ustekinumab and similar medications showed no increased chances of birth defects or miscarriages. 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 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.

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