Ustekinumab (Stelara®)

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

What is ustekinumab?

Ustekinumab (pronounced yoo stek in YOO mab) 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®.

How long does ustekinumab stay in the body? Should I stop taking it before I try to get pregnant?

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.

Do not stop taking any medication without first talking with your healthcare provider. The benefits of taking ustekinumab and treating your autoimmune condition during pregnancy need to be weighed against the possible risks of continuing the medication.

Can taking ustekinumab make it more difficult for me to become pregnant?

This is not clear yet. In an animal study done by the manufacturer, no negative effect on fertility was found. Studies on women have not been done to see if there is any effect on a woman’s ability to become pregnant.

Can taking ustekinumab during my pregnancy cause birth defects?

In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. While animal studies have suggested no increase in 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 woman had a miscarriage and the others went on to deliver healthy full-term infants. The woman with the miscarriage had other general risk factors for a miscarriage. The maker of ustekinumab also reported on 34 women exposed during pregnancy. The chance for birth defects or pregnancy loss was found to be the same as in women who had not taken ustekinumab in pregnancy.

Can I take ustekinumab in the third trimester?

Although more ustekinumab may cross the placenta during the third trimester than in the first trimester, there is very limited information looking at the use of ustekinumab in the third trimester. There are also no official recommendations on third trimester use. The decision to use ustekinumab in the later part of pregnancy should be made with your health care 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 his/her 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 should be 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. The rotavirus vaccine is the only live vaccine that is routinely recommended for infants less than one year of age in the United States.

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

**Can I take ustekinumab while breastfeeding?**

Ustekinumab has not been studied during breastfeeding. Because ustekinumab is a very large protein, it is likely that very little medication would pass into breast milk. Also ustekinumab is not well absorbed by the gut, so any of the medication that gets into breastmilk would be unlikely to enter the baby’s system. Premature babies (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 health care provider about all your breastfeeding questions.

**What if the father of the baby takes ustekinumab?**

There are no studies looking at possible risks to a pregnancy when the father takes ustekinumab. In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at http://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/.

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 or sign up at https://mothertobaby.org/join-study/.

Please click here for references.