



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Ustekinumab (Stelara®)

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. This sheet talks about whether exposure to ustekinumab may increase the risk for birth defects over that background risk. 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 and Crohn's disease, and active psoriatic arthritis. It reduces inflammation by blocking two proteins in the body. 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?

Individuals break down medicines at different rates. On average it takes about 15-46 days for one half of this medicine to leave the body. This means it can take between 2.5- 9 months before most of the medicine 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 health care 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?

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 exposed pregnancies. 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?

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.

Ustekinumab may negatively affect the immune system in the infant exposed during pregnancy. Live vaccines given in the newborn period should be avoided, if possible, in the first year of life. Live vaccines always carry a small chance a person could contract 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. Types of live vaccines include measles-mumps-rubella (MMR), varicella (chicken pox) and rotavirus vaccines. The rotavirus vaccine is the only live vaccine given to infants less than one year of age in the United States.

Rotavirus is one of the leading causes of vomiting and severe diarrhea in children. The rotavirus vaccine is routinely recommended immunization for infants in the US, and is the best way to protect infants against rotavirus disease.

There is a report of a mother treated with a similar medication (infliximab) during pregnancy whose infant received a live BCG vaccine at 3 months of age. The baby later died of a suspected BCG infection that spread throughout the body. However, it is not known if exposure to infliximab was at all related. The live BCG vaccine protects against tuberculosis and is not part of the recommended vaccinations for infants in the United States. This vaccine is used in other countries where tuberculosis infections are common.

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 for use during breastfeeding. Because ustekinumab is a very large protein, it is not likely that very much of the medication would be able to 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 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 <https://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/>.

References Available By Request

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