



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

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

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Infliximab (Remicade®)

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 infliximab 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 infliximab?

Infliximab is a prescription medication used to treat some kinds of autoimmune diseases such as rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, and ulcerative colitis. Infliximab is called a tumor necrosis factor-alpha (TNF) inhibitor because it binds to and blocks TNF, a substance in the body that causes inflammation in the joints, spine, and skin. Infliximab is given as an intravenous (IV) infusion. Infliximab is sold under the brand name Remicade®.

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

Individuals break down medications at different rates. On average, it takes about 7 weeks after the last infusion of infliximab for most of the medication to be cleared from the body. It's recommended that you talk to your health care provider before you stop taking any medication. The benefits of taking infliximab and treating your autoimmune condition during pregnancy need to be compared with the possible risks of continuing the medication.

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

There are currently no reports linking infliximab to fertility problems.

Can taking infliximab during pregnancy increase the risk for miscarriage?

Having an autoimmune disease may increase the chance for miscarriage, which makes it difficult to find out whether the medications used to treat these diseases can also cause miscarriage. While some small studies suggest a higher rate of miscarriage among women treated with infliximab early in pregnancy, other studies do not. A recent study looking at 495 women exposed to a TNF inhibitor early in pregnancy (almost one third of the women were taking infliximab) did not find an increased risk for miscarriage. More research is needed to confirm if this medication is associated with a higher chance of miscarriage.

Can taking infliximab during pregnancy cause birth defects?

The limited data looking at the use of infliximab during pregnancy does not suggest a higher chance for birth defects. An analysis of cases reported to the infliximab safety database did not find an increased risk for birth defects in pregnancies. Most of these women took infliximab during the first trimester or within 3 months before conception. Another study that collected data from 9 different countries looked at 156 women exposed to infliximab during pregnancy, and did not see an increased chance for birth defects. Other small studies of 10, 25, and 32 women who took infliximab during pregnancy also did not find an increased chance for a pattern of birth defects or other problems.

A study published in 2009 looked at birth defects reported in mothers who used a TNF inhibitor during pregnancy. The authors suggested these medications could cause VACTERL association. VACTERL association is a pattern of birth defects that includes vertebral (spine), anal, cardiac (heart), tracheal-esophageal (structures in the neck), renal (kidney), and limb (arms and legs) defects. Two or more of these defects must be found for a baby to be diagnosed with VACTERL association. This study had many problems including limited data, voluntary reporting, and misdiagnosis of VACTERL association. Therefore, it does not support the conclusion that TNF inhibitors cause an increased risk for a pattern of birth defects.

In summary, small studies looking at infliximab use during pregnancy have not shown an increased risk for birth defects. It is also reassuring that a large amount of infliximab is not thought to reach the pregnancy during the first trimester. However, results from more studies are needed before we can be sure of the effects of infliximab on a pregnancy.

Can I take infliximab after the first trimester?

Because infliximab is a big protein, recent information suggests that a large amount of the medication is not able to cross the placenta and reach the baby until later in the second trimester. The placenta is a temporary organ that develops during pregnancy and works as the blood connection between you and your baby. As the pregnancy continues, more infliximab is thought to cross the placenta and reach the developing baby.

At this time, there is limited information looking at the use of infliximab after the first trimester. Although more infliximab may cross the placenta later in pregnancy, there have not been any reports that have shown increased risks to the baby when a mother takes infliximab in the second or third trimester. As of today, there are no official recommendations to either stop or continue the use of infliximab later in pregnancy. The decision to use this medication 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 6 months of age if I take infliximab later in pregnancy?

Most vaccines given in the first 6 months of life are noninfectious and can be given to a baby even if infliximab is present in his/her blood. Noninfectious vaccines are not live vaccines, meaning a person cannot get the infection from the vaccine. Live vaccines, on the other hand, always carry a small chance that a person could contract the infection from the vaccine. However, live vaccines usually contain a weaker (attenuated) form of the virus or bacteria than what you might be exposed to should you come into contact with someone who has the actual infection. Types of live vaccines include measles-mumps-rubella (MMR), varicella (chicken pox), and rotavirus vaccine. The rotavirus vaccine is the only live vaccine given to infants less than 6 months of age in the United States. Rotavirus is one of the leading causes of vomiting and severe diarrhea in children. The rotavirus vaccine is a routine recommended immunization for infants in the U.S., and is the best way to protect your baby against rotavirus disease.

There is a single report of a woman treated with infliximab during pregnancy whose infant received a live bacille Calmette-Guerin (BCG) vaccine at 3 months of age. BCG is a vaccine that protects against tuberculosis (TB). The baby later died of a suspected BCG infection that spread throughout the body. However, it is not known if prenatal exposure to infliximab was at all related. The live BCG vaccine is not usually given in the U.S., but; it is used in other countries where tuberculosis infections are common.

While live vaccines are usually not given to those using TNF inhibitors like infliximab, vaccines protect babies from getting common infections that can sometimes cause serious or even life-threatening illness. Always be sure to let your pediatrician know about any medications or exposures you had during pregnancy or while breastfeeding, including treatment with TNF inhibitors. Your pediatrician may want to check your baby's blood for presence of infliximab before administering a live vaccine. If the medication is still in the baby's blood, the pediatrician can discuss the risks and benefits of giving a live vaccine to your baby with you.

Can I take infliximab while breastfeeding?

Because infliximab is a very large protein, it is not likely that very much of the medication would be able to get into breast milk. Also, infliximab is not well absorbed from the baby's gut, so any of the medication that gets into breast milk, and is swallowed by the baby would be unlikely to enter their system. It is possible that premature babies (born before 37 weeks of pregnancy) may be able to absorb more of the medication through breast milk since their digestive systems are not fully developed. Reports of women who have breastfed while taking infliximab show that only a small amount of the medication is passed into the breast milk. Additionally, a small number of babies exposed to infliximab in breast milk have been followed for up to a year, and no negative effects on development have been seen.

Be sure to talk to your health care provider about all of your breastfeeding questions.

What if the father of the baby takes infliximab?

One study of 10 men taking infliximab found changes in the movement and shape of their sperm. It is not known if these changes would affect fertility. Another small study of 11 men did not find evidence of fertility problems. There were also no birth defects or an increased rate of pregnancy complications reported in another 10 pregnancies when the father of the baby took infliximab before and during the pregnancy.

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 autoimmune diseases 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.

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