Infliximab (Remicade®)

This sheet is about exposure to infliximab in a pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare providers.

What is infliximab?

Infliximab is a medication used to treat autoimmune diseases such as rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, and ulcerative colitis. For more information, please see the MotherToBaby fact sheets on rheumatoid arthritis (https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/), psoriasis and psoriatic arthritis (https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/), and ankylosing spondylitis (https://mothertobaby.org/fact-sheets/ankylosing-spondylitis/).

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 sold under the brand name Remicade®.

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

Studies have not been done to see if infliximab could make it harder for a woman to get pregnant.

I just found out that I am pregnant. Should I stop taking infliximab?

Talk with your healthcare providers before making any changes to how you take your medication. The benefits of taking infliximab and treating your autoimmune condition during pregnancy need to be compared with the possible risks of untreated illness.

Does taking infliximab increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. Having an autoimmune disease may increase the chance for miscarriage, which makes it hard to know if the medications used to treat these diseases can also cause miscarriage. While some small studies suggest a higher chance of miscarriage among people treated with infliximab early in pregnancy, other studies do not. One study looking at 495 people who were pregnant exposed to a TNF inhibitor early in pregnancy (almost one third of them were taking infliximab) did not find an increased chance for miscarriage. In another study of 1850 pregnancies exposed to infliximab, no increased chance for miscarriage was found.

Does taking infliximab 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. Infliximab has not been well studied for use in pregnancy, but the available data does not suggest a higher chance for birth defects. There are multiple studies and some case reports of babies exposed to infliximab during pregnancy with no increased chance for birth defects or other problems.

A study published in 2009 looked at birth defects reported in people who used a TNF inhibitor during pregnancy. The authors suggested these medications could cause VACTERL association, 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. However, 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 chance for a pattern of birth defects. In summary, studies looking at infliximab use during pregnancy have not shown a significantly increased chance for birth defects.

Could taking infliximab cause other pregnancy complications?

Recent information suggests that large amounts infliximab do not cross the placenta to reach the developing baby in the first trimester. (The placenta is a temporary organ that develops during pregnancy and works as the blood connection between you and your baby.) As pregnancies continue, more of the medication is able to cross the placenta. However, just because a medication crosses the placenta does not mean it would harm a pregnancy.

One study found an association between treatment with TNF inhibitors like infliximab and an increased chance for preterm delivery (delivery before 37 weeks of pregnancy), caesarean section, and small size. Another study noted
preterm births and infant complications were more common for pregnant individuals who were exposed to both infliximab and immunosuppressant medications. It is not clear if these effects are related to infliximab, the disease being treated, or a combination of factors.

There have also been case reports of people who used infliximab in the third trimester of pregnancy and delivered healthy babies. The decision to use this medication in the later part of pregnancy should be made with your healthcare provider and be based on your condition and the severity of your symptoms.

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

It is not known if infliximab can cause behavior or learning issues. A recent study reported on 115 children exposed to infliximab during pregnancy. There was no association between negative long-term health outcomes and exposure to infliximab during pregnancy.

**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 they were exposed to infliximab during pregnancy. Noninfectious vaccines are not live vaccines, meaning a person cannot get the infection from the vaccine. Live vaccines carry a small chance that a person could develop the infection from the vaccine. However, live vaccines usually contain a milder form (attenuated) of the virus or bacteria than what you might be exposed to in the community. Types of live vaccines given in the US include measles-mumps-rubella (MMR), varicella (chicken pox), and rotavirus vaccine. Live vaccines are usually not given to adults using TNF inhibitors like infliximab. This is because there is a concern that TNF inhibitors cause immunosuppression (decreased immunity) and therefore increase chance of infection from the live vaccine.

The rotavirus vaccine is the only live vaccine given to infants less than one year of age in the United States. The vaccine series must be started by 15 weeks of age. Rotavirus is one of the leading causes of vomiting and severe diarrhea in children.

If a baby is exposed to infliximab during pregnancy, they might still have the drug in their blood after birth. A healthcare provider may want to check the baby’s blood for infliximab before giving a live vaccine. If the medication is still in the baby’s blood, the healthcare provider can discuss the risks and benefits of giving a live vaccine to your baby. 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 exposure to infliximab during pregnancy 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.

Another study looked into the effect of vaccinations in babies who were exposed to infliximab during pregnancy; no increased chance for infection was reported. Nineteen infants exposed to infliximab during pregnancy received the rotavirus vaccines. Of these, five infants had a fever, and one had diarrhea. This study suggested rates of complications for the infants exposed to infliximab compared to those not exposed to infliximab were similar, and no serious complications were reported. In a recent study, only one infant out of 196 who were exposed to a TNF inhibitor during pregnancy had a negative reaction to a vaccination. The reaction was not life-threatening, and the infant was also exposed to thiopurine (another medication that may be used to treat Crohn's disease or ulcerative colitis) during the pregnancy. Also, it is unclear if the TNF inhibitor used was infliximab or another medication. This study did not suggest an association between exposure to infliximab during pregnancy and negative reactions to vaccines.

**Can I breastfeed while taking infliximab?**

Reports of people who have breastfed while taking infliximab show that only a small amount of the medication enters breast milk. In addition to small levels in milk, infliximab is not well absorbed from the baby’s gut. This means that any of the medication that gets into breast milk and is swallowed by the baby would be unlikely to enter their system. Studies on a small number of babies exposed to infliximab through breast milk that were followed for up to a year did not report negative effects on development. It is possible that babies born preterm may absorb more of the medication through breast milk compared to full-term babies (born after 37 weeks of pregnancy) since their digestive systems are not fully developed. Recommendations for babies born prematurely might be different. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

**I take infliximab. Can it make it harder for me to get my partner pregnant or increase the chance of birth defects?**
One study of 10 males taking infliximab found changes in the shape and movement of their sperm. It is not known if these changes would affect fertility. Another small study of 11 males 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 male partner took infliximab before and during the pregnancy.

In general, exposures that fathers and 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 in pregnancy. If you would like to learn more about this study, please call 1-877-311-8972 or visit https://mothertobaby.org/join-study/

Please click here for references.