Infliximab

This sheet is about exposure to infliximab 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 providers.

What is infliximab?

Infliximab is a medication that has been used to treat 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. TNF is a substance in the body that causes inflammation in the joints, spine, and skin. Some brand names of infliximab are Avsola®, Inflectra®, Ixifi®, Remicade®, and Reflexis®.

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/), ankylosing spondylitis (https://mothertobaby.org/fact-sheets/ankylosing-spondylitis/), and inflammatory bowel disease (https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/).

Sometimes when women 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 infliximab. Can it make it harder for me to get pregnant?

It is not known if infliximab can make it harder to get pregnant.

Does taking infliximab increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Some studies suggest a higher chance of miscarriage among women treated with infliximab early in pregnancy, and other studies do not.

A study looking at 495 women who were exposed to a TNF inhibitor early in pregnancy did not find an increased chance of miscarriage. Almost one third (1 in 3) of women in the study were taking infliximab. Another study of 1,850 pregnancies exposed to infliximab also found no increased chance of miscarriage.

Having an autoimmune disease can increase the chance of miscarriage. This makes it hard to know if any miscarriages are from the medications, underlying diseases, or other factors.

Does taking infliximab 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 infliximab, might increase the chance of birth defects in a pregnancy. Using infliximab in pregnancy is not expected to increase the chance of birth defects above the background risk. Several studies did not find a higher chance for birth defects when infliximab was used during pregnancy. Additionally, very little infliximab is expected to cross the placenta and reach the developing pregnancy during the first trimester (when many of the fetal organs and body structures are forming). More of the medication can cross the placenta starting in the second trimester.

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

Some studies have suggested that taking TNF inhibitors like infliximab during pregnancy could increase the chance for preterm delivery (birth before week 37) and poor growth of the baby. However, since some of the conditions that TNF inhibitors are used to treat can also increase the chance of these issues, it is not clear if these effects are related to the medications, the underlying diseases being treated, or a combination of factors. Most studies have not shown an increased chance of preterm delivery, poor growth of the baby, or newborn complications following exposure to infliximab in pregnancy.

Does taking infliximab in pregnancy affect future behavior or learning for the child?

A study of children with prenatal exposure to infliximab and other TNF inhibitors looked at the children's development at 12, 24, 36, and 48 months of age. There were no increased delays in communication, fine motor skills (movements like picking up small toys), gross motor skills (big movements like crawling and running), personal social skills, or problem solving. Another study followed 115 children up to age 5 years and found no association between exposure to infliximab during pregnancy and effects on their growth, rates of infections, autoimmune diseases, or cancers.

Can my baby receive live vaccines before 6 months of age if I take infliximab later in pregnancy?

Since infliximab may suppress the immune system of the person taking it, there is a theoretical (not proven) concern that the same thing could happen to the baby if they are exposed to the medication during pregnancy. If someone has a weakened immune system, they might be more likely to develop an infection from a live vaccine since live vaccines contain a small amount of live virus.

In the United States, the only live vaccine typically given to babies in the first year of life is the rotavirus vaccine. The American Academy of Pediatrics (AAP) says that rotavirus vaccination of infants can be considered when mothers received treatment during pregnancy with infliximab. Your healthcare provider and baby's pediatrician can talk with you about your child's vaccines and what is best for your situation.

All other vaccines given in the first year of life are usually inactivated. Inactivated vaccines do not contain live virus, so they cannot cause the disease they protect against. Most babies exposed to infliximab in pregnancy can get inactivated vaccines in the first year of life.

Breastfeeding while taking infliximab:

Infliximab is a large protein, which means very little of the medication is expected to get into breast milk. Infliximab is not well absorbed when swallowed, so any small amounts that a baby swallows in the milk are unlikely to enter their bloodstream. Studies on a small number of infants exposed to infliximab through breast milk did not report negative effects on development up to 1 year of age. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

While some studies of men taking infliximab found changes in the shape and movement of their sperm, studies have not found evidence of long-term fertility problems (ability to get a woman pregnant) due to the medication. Having poorly controlled inflammatory disease could also affect sperm. Studies do not suggest an increased chance of birth defects or pregnancy complications when male partners take infliximab before and during the pregnancy. In general, exposures that men 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.

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