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## **Infliximab (Remicade<sup>®</sup>) and Pregnancy**

This sheet talks about the risks that exposure to infliximab can have during pregnancy. With each pregnancy, all women have a 3% to 5% chance of having a baby with a birth defect. 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 (TNF) inhibitor because it binds 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 marketed under the brand name Remicade<sup>®</sup>.

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

On average, it takes about seven weeks after the last infusion of infliximab for all of the medication to be cleared from the body. You should not stop taking any medication without first talking with your doctor. The benefits of taking infliximab and treating your autoimmune condition during pregnancy need to be weighed against the possible risks of continuing the medication.

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

There are no studies looking at whether infliximab affects fertility. Therefore, it is not

known if taking infliximab would make it more difficult for a woman to get pregnant.

### ***Can taking infliximab during my pregnancy cause birth defects?***

Very little research has been done on infliximab use during pregnancy. In a survey sent to rheumatologists, the doctors reported no increase in birth defects or miscarriage rates in 417 women exposed to infliximab or another TNF inhibitor during pregnancy. About one third of these women continued to take the medication throughout pregnancy. An analysis of cases reported to the infliximab safety database did not find an increased risk in birth defects or miscarriage rates in 78 pregnancies; most of these women took infliximab during the first trimester or within three months prior to conception. Other small studies have not found an increased number of birth defects in babies born to women taking infliximab during pregnancy.

One 2009 paper reviewed birth defects reported in babies born to mothers who used a TNF inhibitor. The authors suggested that these medications might cause a pattern of birth defects known as VACTERL association (Vertebral, Anal, Tracheal-Esophageal, and Renal birth defects). However, only one case of VACTERL association was found in this series of birth defect reports. Therefore, this review does not support the conclusion that TNF inhibitors cause any 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. However, results from more studies are needed in order to determine if infliximab is safe to use during pregnancy.

### ***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 pass into breast milk. In addition, infliximab is not well absorbed from the gut so any of the medication that gets into breast milk would be unlikely to enter the baby's system. It is possible that premature babies with immature digestive systems may be able to absorb more of the medication through breast milk. A few reports of women breastfeeding while taking infliximab showed no significant transfer of the medication into their breast milk. Be sure to discuss options concerning breastfeeding with your health care provider.

### ***What if the father of the baby takes infliximab?***

One study of ten men taking infliximab found changes in the movement and shape of their sperm. It is not known if these changes would affect fertility. There were no birth defects or an increased rate of pregnancy complications reported in ten pregnancies when the father of the baby took infliximab before and during the pregnancy. In general, exposure of the father is unlikely to increase the risk to a pregnancy because, unlike the mother, the father does not share a blood connection with the developing baby.

***OTIS 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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*If you have questions about the information on this fact sheet or other exposures during pregnancy, call OTIS at 1-866-626-6847.*