



For more information about the Organization of Teratology Information Specialists or to find a service in your area, call (866) 626-6847 or visit us online at: www.OTISpregnancy.org.

Adalimumab (Humira®) and Pregnancy

This sheet talks about the risks that exposure to adalimumab 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 adalimumab?

Adalimumab is a prescription medication used to treat some kinds of autoimmune diseases such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and Crohn's disease. Adalimumab 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. Adalimumab is given as an injection directly below the skin. Adalimumab is marketed under the brand name Humira®.

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

On average, it takes about ten weeks after the last injection of adalimumab 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 adalimumab and treating your autoimmune condition during pregnancy need to be weighed against the possible risks of continuing the medication.

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

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

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

Can taking adalimumab during my pregnancy cause birth defects?

Very little research has been done on adalimumab 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 adalimumab or another TNF inhibitor during pregnancy. About one third of these women continued to take the medication throughout pregnancy. Two studies reporting on the outcomes of 86 and 99 pregnancies with exposure to adalimumab did not find an increased risk for a pattern of birth defects. There have been a few other reports of normal outcomes after women took adalimumab 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 adalimumab use during pregnancy have not shown an increased risk for birth defects. However, results from more studies are needed

in order to determine if adalimumab is safe to use during pregnancy.

Can I take adalimumab while breastfeeding?

There are no controlled studies looking at how much adalimumab passes into human breast milk. Because adalimumab 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, adalimumab 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. Two reports of women breastfeeding while taking adalimumab showed no harmful side effects in their infants. Be sure to discuss options concerning breastfeeding with your health care provider.

What if the father of the baby takes adalimumab?

There are no studies looking at possible risks to a pregnancy when the father takes adalimumab. 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. For more information, please see the OTIS fact sheet about Paternal Exposures at <http://otispregnancy.org/pdf/paternal.pdf>.

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.

November 2009.
Copyright by OTIS.
Reproduced by permission.



References:

Carter JD, Ladhani A, Ricca LR, Valeriano J, Vasey FB. 2009. A Safety Assessment of Tumor Necrosis Factor Antagonists During Pregnancy: A Review of the Food and Drug Administration Database. *The Journal of Rheumatology* 36:3.

Carter JD, Valeriano J, Vasey FB. 2006. Tumor necrosis factor-alpha inhibition and VATER association: a causal relationship. *J Rheumatol* 33(5):1014-7.

Hale TW. 2004. *Medications and Mother's Milk* Eleventh Edition. Texas: Pharmasoft Publishing.

Johnson DL, et al. 2009. Pregnancy outcomes in women exposed to adalimumab: an update on the Autoimmune Diseases in Pregnancy Project. Abstract presented at the American College of Gastroenterology 2009 Annual Scientific Meeting, San Diego, CA, October 23rd – 28th.

Mishkin DS, et al. 2006. Successful use of adalimumab (Humira) for Crohn's disease in pregnancy. *Inflamm Bowel Dis.* 12:827-828.

Orozco C, et al. 2005. Safety of TNF inhibitors during pregnancy in patients with inflammatory arthritis. Abstract presented at 69th Annual Meeting, Am College of Rheum, San Diego, CA, November 13th-17th.

Roux CH, et al. 2006. Pregnancy in rheumatology patients exposed to anti-tumour necrosis factor (TNF)-{alpha} therapy. *Rheumatology* 46:695-698.

Vesga L, Terdiman JP, and Mahadevan U. 2005. Adalimumab use in pregnancy. *Gut* 54:890.

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