Adalimumab (Humira®) and Pregnancy

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 adalimumab 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 professional.

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 sold under the brand name Humira®.

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

Individuals break down medicines at different rates. On average, it takes about ten weeks after the last injection of adalimumab for all 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 adalimumab and treating your autoimmune condition during pregnancy need to be compared with the possible risks of continuing the medication.

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

There are no reports linking adalimumab to fertility problems. Adalimumab is being studied to see if it may be used with other therapies to improve the success rates of certain fertility treatments in some women.

Can taking adalimumab during my pregnancy cause birth defects?

Adalimumab use during pregnancy is not well studied. 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 also found no increased risk for a pattern of birth defects. There have been several other reports of babies born without birth defects or other problems after women took adalimumab during pregnancy.

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 defects in this pattern must be found for a baby to be diagnosed with VACTERL. Also, other syndromes or genetic disorders must be ruled out before a diagnosis of VACTERL can be made. Due to the study design, limited data, and voluntary reporting, this review does not support the conclusion that TNF inhibitors cause an 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 a pattern of birth defects. It is also reassuring that a large amount of adalimumab 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 adalimumab on a pregnancy.

Can I take adalimumab in the third trimester?

Recent information suggests that large amounts of the medication do not cross the placenta and 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 the
pregnancy continues, more of the medication is able to cross the placenta.

Although more adalimumab is thought to cross the placenta during the third trimester than in the first trimester, there have not been any reports that have shown risks to the baby when a mom takes adalimumab in the third trimester. At this time, there is very limited information looking at the use of adalimumab in the third trimester. There are also no official recommendations regarding third trimester use. The decision to use adalimumab 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 one year of age if I take adalimumab later in pregnancy?

Most vaccines given in the first 6 months of life are noninfectious and can be given to a baby even if adalimumab is present in his/her blood. Noninfectious vaccines are not live vaccines, meaning a person cannot get the infection from the vaccine. Live vaccines always carry a small chance a person could contract 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 include measles-mumps-rubella (MMR), varicella (chickenpox) and rotavirus vaccine. The rotavirus vaccine is the only live vaccine given to infants less than one year 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 US, and is the best way to protect infants against rotavirus disease.

There is a single report of a mother treated with another TNF inhibitor (infliximab) during pregnancy whose infant received a live BCG vaccine at 3 months of age. The baby later died of a suspected BCG infection that spread throughout the body. However, it is not known if exposure to infliximab was at all related. The live BCG vaccine protects against tuberculosis and is not part of the recommended vaccinations for infants in the United States. This vaccine is not usually given in the US; it is used in other countries where tuberculosis infections are common.

Always be sure to let your pediatrician know of any medications or exposures you had during pregnancy or breastfeeding, including treatment with TNF inhibitors. Your pediatrician can discuss the risks and benefits of live vaccines with you.

Can I take adalimumab while breastfeeding?

It is thought that because adalimumab is a very large protein, very little of the medication would be able to pass into breast milk. Five reports of mothers who breastfed their infants while using adalimumab have suggested that adalimumab levels in breast milk are very low. Also, adalimumab is not well absorbed by 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 (born before 37 weeks) with digestive systems that are not fully developed may be able to absorb more of the medication through breast milk. Be sure to discuss all your choices for breastfeeding with your health care provider.

What if the father of the baby takes adalimumab?

One study reported that 15 men taking a TNF inhibitor for spondylarthitis (SpA) had the same sperm quality as men with SpA who were not taking a TNF inhibitor. Only one of the fifteen men was taking adalimumab, but this information suggests that if a man takes adalimumab, his fertility would not be affected.

In general, exposures that fathers have are unlikely to increase the risk to a pregnancy because unlike the mother, (who shares the placenta with the baby) the father does not share a blood connection with the developing baby. For more information, please see the Paternal Exposures fact sheet at http://www.mothertobaby.org/files/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.

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References Available By Request

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