



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Adalimumab (Humira®)

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 provider.

What is adalimumab?

Adalimumab is a prescription medication that has been used to treat 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 an adult, non-pregnant body. There is one case report of a woman who stopped adalimumab at week 16 of her pregnancy and the medicine was able to be measured in her blood and the umbilical cord blood at time of delivery 21 weeks later. 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 any 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. One study did not notice an increased chance for miscarriage among 495 women taking a TNF inhibitor (150 used adalimumab). 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. Three other studies reporting on the outcomes of 23, 86 and 99 pregnancies with exposure to adalimumab also found no increased risk for a pattern of birth defects. In addition, there have been several other case 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, one study among 495 women taking a TNF inhibitor (150 used adalimumab) for an autoimmune

disease reported a slightly higher chance for a birth defect. The study compared these pregnancies to the pregnancies of women who did not have an autoimmune disease; therefore, it is not clear if the medication or the underlying disease explains the slightly higher risk. 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 this medication 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.

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 (chicken pox) 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 (to prevent tuberculosis) 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. This vaccine is not usually given in the US; it is used in other countries where tuberculosis infections are common.

While live vaccines are usually not given to those using TNF inhibitors like adalimumab, vaccines protect babies from getting common infections that can sometimes cause serious or even life threatening illness in young children.

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?

Five reports of mothers who breastfed their infants while using adalimumab have suggested that adalimumab levels in breast milk are very low. There are a small number of reports of healthy newborns who were breastfed by a mother taking adalimumab. 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 from the gut. 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 (1 was using adalimumab) for spondylarthritis (SpA) had the same sperm quality as men with SpA who were not taking a TNF inhibitor. Another study on 23 men taking a TNF inhibitor (14 using adalimumab) for 3 to 12 months for ankylosing spondylitis (AS) did not find any effect on sperm quality. Furthermore, while a report in 10 men with SpA found that semen quality was poorer than in healthy controls at the beginning of the study, they actually found an improvement in semen quality after 1 year of therapy with adalimumab. This information suggests that adalimumab would be unlikely to affect a man's fertility (ability to get partner pregnant). In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more

information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at:
<https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/>.

MotherToBaby is currently conducting studies looking at autoimmune diseases and the medications used to treat these diseases in pregnancy. If you are interested in taking part in one of these studies, please call 1-877-311-8972.

References Available By Request

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