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®) 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 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 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.