# Adalimumab (Humira®)

This sheet is about exposure to adalimumab in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

# What is adalimumab?

Adalimumab is a medication that has been used to treat autoimmune diseases such as rheumatoid arthritis, psoriatic arthritis, plaque psoriasis, ankylosing spondylitis, and inflammatory bowel disease (IBD) which includes ulcerative colitis and Crohn's disease. Adalimumab is called a tumor necrosis factor (TNF) inhibitor because it binds and blocks TNF. TNF is a substance in the body that causes inflammation in the joints, spine, and skin. Adalimumab is sold under the brand name Humira®.

Sometimes when women find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take your medication. Autoimmune diseases in pregnancy, especially when not well treated, could increase the risk for pregnancy-related problems. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

MotherToBaby has fact sheets on the following medical conditions:

Ankylosing spondylitis: https://mothertobaby.org/fact-sheets/ankylosing-spondylitis/,

Inflammatory bowel disease (IBD): https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/,

Psoriasis and psoriatic arthritis: https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/,

Rheumatoid arthritis: https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/.

# I am taking adalimumab, but I would like to stop taking it before getting pregnant. How long does the drug stay in my body?

People eliminate medication at different rates. In healthy adults, it takes up to 12 weeks (3 months), on average, for most of the adalimumab to be gone from the body. There is one case report of a person who stopped adalimumab at week 16 of their pregnancy. Medication levels were found in their blood and the umbilical cord blood at delivery 21 weeks later.

## I take adalimumab. Can it make it harder for me to get pregnant?

It is not known if adalimumab can make it harder to get pregnant. Adalimumab is being studied to see if it might be used with other therapies to improve the success rates of certain fertility treatments.

## Does taking adalimumab increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Adalimumab is not expected to increase the chance of miscarriage.

## Does taking adalimumab increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. One study of 495 women taking a TNF inhibitor (147 used adalimumab) for an autoimmune disease reported a slightly higher chance for birth defects. The study compared these pregnancies to the pregnancies of women who did not have an autoimmune disease. It is not clear if the medication or the underlying disease caused the slightly higher chance. Multiple other studies reporting on the outcomes of almost 700 pregnancies with exposure to adalimumab, found no increased chance for a pattern of birth defects.

In summary, studies looking at adalimumab use during pregnancy have not shown an increased chance of a pattern of birth defects.

## Does taking adalimumab in pregnancy increase the chance of other pregnancy-related problems?

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More adalimumab is thought to cross the placenta during the third trimester than in the first trimester of pregnancy. Studies looking at over 200 women who were pregnant and continued TNF inhibitors, including adalimumab, into or throughout the third trimester of pregnancy compared to pregnant individuals who stopped before the third trimester did not find an increased chance of preterm birth (birth before week 37). Studies of over 600 women who continued TNF inhibitors into or through the third trimester were not associated with low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth). The decision to use adalimumab in the later part of pregnancy may be based on your condition and how serious your symptoms are.

#### Does taking adalimumab in pregnancy affect future behavior or learning for the child?

It is not known if adalimumab increases the chance of behavior or learning issues.

#### Can my baby receive live vaccines before one year of age if I take adalimumab later in pregnancy?

Because some TNF inhibitors may suppress the immune system of the person taking it, there has been a theoretical concern that the same thing could happen to the baby if they are exposed during pregnancy. If someone has a weakened immune system they might be more likely to develop an infection from a live vaccine. Live vaccines contain a small amount of live virus. Inactivated vaccines do not contain live virus, so they cannot cause the disease they protect against. In the United States, rotavirus is the only live vaccine routinely given in the first year of life. Most people can get inactivated vaccines in the first year of life.

For adalimumab, studies have shown no increase in infection rates in children after delivery, and up to 12 months of age. Talk with your child's healthcare provider about your exposure to adalimumab during pregnancy. They can talk with you about the vaccines your child should receive and the best time for your child to receive them.

#### Breastfeeding while taking adalimumab:

Available data suggests that adalimumab levels in breast milk are very low. There are a small number of reports of healthy newborns who were exposed to adalimumab through breastmilk. Adalimumab is usually not well absorbed by the gut, so the amount of the medication absorbed by the baby from breastmilk is expected to be low. If you think that the baby has symptoms (vomiting, frequent infections), contact the child's healthcare provider. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

#### If a man takes adalimumab, could it affect fertility or increase the chance of birth defects?

Two small studies have shown that TNF inhibitors might change how the sperm works, however, most other studies have not shown changes in fertility (ability to get a woman pregnant). In general, exposures that men have are unlikely to increase the risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

#### Please click here for references.

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 or sign up at https://mothertobaby.org/join-study/.



#### Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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