# Adalimumab (Humira®)

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

## *What is adalimumab?*

Adalimumab is a medication 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 a tumor necrosis factor (TNF) inhibitor, meaning it blocks TNF, a substance that causes inflammation in the joints, spine, and skin. Adalimumab is sold under the brand name Humira®.

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

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 of 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.

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

The time it takes the body to metabolize (process) medication is not the same for everyone. In healthy non-pregnant adults, it takes up to 12 weeks (3 months), on average, for most of the adalimumab to be gone from the body. One case report described a woman who stopped adalimumab at 16 weeks of pregnancy. At delivery, 21 weeks later, the medication was still found in her blood and in the baby's umbilical cord blood.

## *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. Studies are ongoing to see whether adalimumab might improve some fertility treatment outcomes.

## *Does taking adalimumab increase the chance of miscarriage?*

Miscarriage is common and can occur in any pregnancy for many different reasons. Most available studies on adalimumab do not suggest an increased chance of miscarriage.

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

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at research studies to try to understand if an exposure, like adalimumab, might increase the chance of birth defects in a pregnancy.

One study of 495 women taking a TNF inhibitor (147 on adalimumab) suggested a slightly higher chance of birth defects compared to women without autoimmune disease. It is unclear whether this was due to the medication or the underlying disease. Other studies of nearly 700 pregnancies exposed to adalimumab found no increased chance of birth defects.

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

Adalimumab may pass through the placenta more in the third trimester than in the first. Studies of women who continued TNF inhibitors, including adalimumab, into the third trimester did not show a higher chance of preterm

birth (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth). You and your healthcare provider can decide whether to use adalimumab later in pregnancy, depending on your condition and symptoms.

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

One study that looked at infants exposed to TNF inhibitors (including adalimumab) in pregnancy throughout their first year of life did not find an increased chance of behavior or learning problems.

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

Some TNF inhibitors, like adalimumab, may affect the immune system. This raised a theoretical concern (not proven) that babies exposed during pregnancy could also have weaker immunity. 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 vaccines and the best timing for your child after your exposure to adalimumab during pregnancy.

### *Breastfeeding while taking adalimumab:*

The amount of adalimumab that passes into breastmilk is low. Also, 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. There are a small number of reports of healthy newborns who were exposed to adalimumab through breastmilk. If you think the baby has symptoms (vomiting, frequent infections), contact the child's healthcare provider. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

Two small studies suggest TNF inhibitors might affect sperm function, but most studies have not shown an effect on fertility (ability to make healthy sperm). Studies have not been done to see if adalimumab could increase the chance of birth defects. In general, exposures that fathers or sperm donors 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.



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