



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

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

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Etanercept (Enbrel®)

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 etanercept 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 etanercept?

Etanercept is a prescription medication used to treat some autoimmune diseases such as rheumatoid arthritis, ankylosing spondylitis, psoriasis, psoriatic arthritis and juvenile rheumatoid arthritis. Etanercept 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. Etanercept is given as an injection directly below the skin. Etanercept is sold under the brand name Enbrel®.

How long does etanercept 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 three to four weeks after the last injection of etanercept for almost 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 etanercept and treating your autoimmune condition during pregnancy need to be weighed against possible risks of continuing the medication.

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

There are no reports linking etanercept to fertility problems. Etanercept 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 etanercept during my pregnancy cause birth defects?

Etanercept use during pregnancy is not well studied. In a survey sent to rheumatologists, the doctors reported no increase in birth defects or miscarriage in 417 women exposed to etanercept or another TNF inhibitor during pregnancy. About one third of these women continued to take the medication throughout pregnancy. Also, five small studies looking at 20, 25, 56, 83 and 100 women taking etanercept in the first trimester found no increased chance for a pattern of birth defects.

A study published in 2009 looked at birth defects reported in mothers who used a TNF inhibitor during pregnancy. The authors suggested that 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.

A 2015 study reported on 495 pregnancies exposed to TNF-alpha inhibitors, with 111 exposed to etanercept. They found a small increased chance of birth defects and preterm delivery when looking at all of the TNF-alpha inhibitor medications. However, this study did not compare pregnancy outcomes to women who had similar medical conditions but were not taking TNF-alpha inhibitors. Therefore, this study cannot determine if the problems reported were due to the medications or the diseases being treated.

In summary, most studies looking at etanercept use during pregnancy have not shown an increased chance for a pattern of birth defects. It is also reassuring that a large amount of etanercept is not thought to reach the pregnancy during the first trimester. However, results from more studies are needed before we can be certain of the effects of

etanercept on a pregnancy.

Can taking etanercept during my pregnancy cause pregnancy complications such as preterm delivery?

One study found that women who had rheumatoid arthritis and were taking etanercept during pregnancy were more likely to deliver before 37 weeks of pregnancy (premature) and have babies with lower birth weight than women who were not taking etanercept and did not have rheumatoid arthritis. This study also found that these risks were increased for women with rheumatoid arthritis who did not take a TNF inhibitor during pregnancy. So, it may be that the autoimmune condition itself or

use of another medication besides etanercept increased the chance for having a premature or low birth weight baby rather than use of etanercept specifically.

Can I take etanercept in the third trimester?

Because etanercept is a large protein, recent information suggests that a significant amount of the medication is not able to cross the placenta and reach the developing baby until the second 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 etanercept may cross the placenta during the third trimester than in the first trimester, there have not been any reports that have shown increased risks to the baby when a mom takes etanercept in the third trimester. At this time, there is very limited information looking at the use of etanercept in the third trimester. There are also no official recommendations regarding third trimester use. The decision to use etanercept 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 etanercept later in pregnancy?

Most vaccines given in the first 6 months of life are noninfectious and can be given to a baby even if etanercept 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. 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 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.

While live vaccines are usually not given to those using TNF inhibitors like etanercept, 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 and breastfeeding, including treatment with TNF inhibitors. Your pediatrician can discuss the risks and benefits of live vaccines with you.

Can I take etanercept while breastfeeding?

Four reports of mothers who breastfed their infants while using etanercept have suggested that etanercept levels in breast milk are very low. Two of these reports looked at the amount of etanercept in the baby's blood from breast milk and found the levels were undetectable. One of the infants was followed to 3 years of age and no harmful effects were reported.

These reports support the idea that, because etanercept is a very large protein, very little of the medication is expected to pass into breast milk. Also, etanercept is not well absorbed from 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 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 etanercept?

Two small studies reported that men taking etanercept for spondylarthritis (SpA) had the same sperm quality as men with SpA who were not taking a TNF inhibitor. This early information suggests that if a father takes etanercept, fertility would not be affected. 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:

<http://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

MotherToBaby 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.

References Available By Request

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