



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 medications 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 is 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 needs to be weighed against any possible risks of continuing the medication.

Can taking etanercept make harder for me to get 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 a miscarriage or birth defects?

The authors of a study published in 2009 suggested that use of TNF inhibitors during pregnancy could cause a pattern of birth defects. However, due to limitations of the study design and the amount of data collected, this review does not support the conclusion that TNF inhibitors cause an increased risk for these defects.

In contrast to the above study, most studies on etanercept use during pregnancy do not suggest an increase in the chance of birth defects. For example, a study published in 2017 found that 337 women treated with etanercept during pregnancy did not have higher rates of birth defects or miscarriage compared to similar groups of women who were not treated with etanercept. Rheumatologists responding to a study survey 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. At least six smaller studies (each looking at fewer than 100 women taking etanercept in the first trimester) have not found an increased chance for a pattern of birth defects.

Two studies that included 319 and 344 infants whose mothers had taken etanercept during pregnancy reported a higher rate of birth defects compared to the infants of women with autoimmune diseases who did not take a TNF inhibitor during pregnancy. However, there was not a particular pattern to the birth defects, which is needed to show an association between the medication and the birth defects. Also, the women who used etanercept might have had more severe disease than the women who did not use it, which could have affected their outcomes. A 2015 study reported on 495 pregnancies exposed to TNF inhibitors, with 140 of those exposed to etanercept. This study found a small increased chance of birth defects and preterm delivery when looking at all of the TNF inhibitor medications. However, the study did not compare these pregnancy outcomes to women who had similar medical conditions but were not taking TNF 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 developing baby during the first trimester when most of the baby's major organs and body structures are forming.

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

Two studies found that women with rheumatoid arthritis, chronic inflammatory arthritis or psoriasis were more likely to deliver before 37 weeks of pregnancy (preterm) and have babies with lower birth weight than women who did not have these medical conditions. This was true for the women with medical conditions who used etanercept and those who did not. This suggests that the autoimmune conditions themselves or use of another medication besides etanercept increased the chance for having a preterm delivery or low birth weight baby rather than the use of etanercept specifically.

Can I take etanercept in the third trimester?

Like other TNF inhibitors, etanercept can cross the placenta and reach the developing baby beginning in the second trimester and even more so in the third trimester. The placenta is a temporary organ that develops during pregnancy and works as the blood connection between mother and baby. Limited information looking at the use of etanercept in the third trimester has not shown increased risks to the baby. The decision to use etanercept in the later part of pregnancy should be made with your healthcare provider and may be based on your condition and the severity of your symptoms.

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

Noninfectious (non-live) vaccines can be given to a baby even if etanercept is present in his/her blood. Most vaccines given in the first 6 months of life are noninfectious.

Live vaccines usually contain a mild (attenuated) form of the virus or bacteria that it vaccinates against. Live vaccines always carry a small chance a person could contract the infection from the vaccine. 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 the United States, the rotavirus vaccine is the only live vaccine given to infants less than one year of age. Rotavirus is one of the leading causes of vomiting and severe diarrhea in children. 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?

Etanercept is a large protein, so very little of the medication is expected to pass into breast milk. The medication is also not well absorbed from the gut, so any etanercept that gets into breast milk would most likely pass through the baby's body without getting into their bloodstream. Premature babies with digestive systems that are not fully developed may be able to absorb more of the medication through breast milk.

The information on taking etanercept while nursing a child is very limited. Four reports of mothers who breastfed their infants while using etanercept suggest 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.

A small study looked at 5 breastfeeding infants whose mothers were treated with etanercept, and compared them to breastfeeding infants whose mothers had the same medical conditions but were not being treated with a TNF inhibitor. The study found no differences in the infants' growth, development, response to vaccinations, or illnesses in the first

year of life.

While the available information is reassuring, the risk to the breastfed infant is still unknown. Be sure to talk to your health care provider about all your breastfeeding questions.

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 taking etanercept would not affect a man's fertility. 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/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 or sign up at <https://mothertobaby.org/join-study/>.

Please click [here](#) to view references.

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