Etanercept (Enbrel®)

This sheet is about exposure to etanercept 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 etanercept?

Etanercept is a medication that has been 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 sold under the brand name Enbrel®.

Sometimes when people 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. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy. If not treated or well-controlled, these conditions may increase risks to a pregnancy.

For more information, please see the MotherToBaby fact sheets on rheumatoid arthritis at https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/, ankylosing spondylitis at https://mothertobaby.org/fact-sheets/ankylosing-spondylitis/, and psoriasis/psoriatic arthritis at https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/.

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

People eliminate medications at different rates. In healthy adults, it takes about 3 to 4 weeks after the last injection of etanercept, on average, for most of the medication to be gone from the body.

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

Studies have not been done to see if etanercept can make it harder to get pregnant. However, etanercept is being studied to see if it might help to improve the success rates of certain fertility treatments.

Does taking etanercept increase the chance of miscarriage?

Miscarriage can occur in any pregnancy for many different reasons. One study found that 337 people treated with etanercept during their pregnancy did not have a higher chance of miscarriage compared to similar groups of people who were not treated with etanercept in pregnancy. Also, no increase in miscarriage was reported in 417 people exposed to etanercept or another TNF inhibitor during pregnancy.

Does taking etanercept 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. Most studies on etanercept use during pregnancy do not suggest an increased chance of birth defects above the background risk.

At least 6 studies (each looking at 100 people, or less, who took etanercept in the first trimester of pregnancy) have not found an increased chance for a pattern of birth defects. In addition, a study that included 2,116 people who reported using etanercept during pregnancy did not find an increased chance of birth defects.

There were 2 studies, that included 663 infants exposed to etanercept during pregnancy, that reported a higher rate of birth defects compared to the infants of people with autoimmune diseases who did not take a TNF inhibitor during pregnancy. However, there was no pattern of birth defects. Also, the people who used etanercept might have had more severe disease than the people who did not use it, which could have affected the outcomes.

A study looking at 495 pregnancies exposed to TNF inhibitors (140 exposed to etanercept) found a small increased chance of birth defects when looking at all the TNF inhibitor medications. However, the study did not compare these pregnancy outcomes to those who had similar medical conditions but were not taking TNF inhibitors. This study cannot

determine if the problems reported were due to the medications or the diseases being treated.

In summary, most of the information from studies looking at etanercept use during pregnancy have not shown an increased chance for a pattern of birth defects.

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

A study looking at 495 pregnancies exposed to TNF inhibitors (140 exposed to etanercept) found a small increased chance of preterm delivery (birth before week 37) when looking at all the TNF inhibitor medications. However, the study did not compare these pregnancy outcomes to those who had similar medical conditions but were not taking TNF inhibitors. This study cannot determine if the problems reported were due to the medications or the diseases being treated. Another study including 2,116 people who reported using etanercept during pregnancy did not find an increased chance of pregnancy complications.

Three studies found that people with rheumatoid arthritis, chronic inflammatory arthritis, or psoriasis were more likely to have preterm delivery and have babies with lower birth weight than people who did not have these medical conditions. This was true for the people with medical conditions who used etanercept and those who did not. This makes it hard to know if the autoimmune conditions themselves or use of another medication besides etanercept increased the chance for these issues.

More etanercept is thought to cross the placenta during the second and third trimesters than in the first trimester of pregnancy. Limited information looking at the use of etanercept in the third trimester has not shown increased risks to the fetus.

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

Studies have not been done to see if etanercept can cause behavior or learning issues for the child.

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

Since etanercept might suppress the immune system of the person taking it, there is 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 may 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.

Talk with your child's healthcare provider about your exposure to etanercept 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 etanercept:

Use of etanercept while breastfeeding is not well-studied. This medication is not well-absorbed from the gut. It is expected that any etanercept that gets into breast milk would most likely pass through the baby's body without getting into their bloodstream. Information on 10 people taking etanercept while breastfeeding suggests that the levels of etanercept 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 the lab test could not measure any etanercept in their blood. One of the infants was followed to 3 years of age and no harmful effects were reported.

A small study looked at 5 infants exposed to etanercept through breastmilk and compared them to breastfeeding infants of people who had the same medical conditions but were not taking a TNF inhibitor medication. The study found no differences in the infants' growth, development, response to vaccinations, or illnesses in the first year of life. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a male takes etanercept, could it affect fertility or increase the chance of birth defects in a partner's pregnancy?

Two small studies reported that males taking etanercept for spondylarthritis (SpA) had the same sperm quality as males with SpA who were not taking a TNF inhibitor. This suggests etanercept would not affect male fertility (ability to get partner pregnant). In general, exposures that fathers or sperm donors have are unlikely to increase 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.

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

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