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Etanercept (Enbrel[®]) and Pregnancy

This sheet talks about the risks that exposure to etanercept can have during pregnancy. With each pregnancy, all women have a 3% to 5% chance of having a baby with a birth defect. 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 kinds of 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, 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 marketed under the brand name Enbrel[®].

How long does etanercept stay in the body? Should I stop taking it before I try to get pregnant?

On average, it takes about three weeks after the last injection of etanercept for all of the medication to be cleared from the body. You should not stop taking any medication without first talking with your doctor. The benefits of taking etanercept and treating your autoimmune condition during pregnancy need to be weighed against the possible risks of continuing the medication.

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

There are no studies looking at whether etanercept affects fertility. Therefore, it is not

known if taking etanercept would make it more difficult for a woman to get pregnant.

Can taking etanercept during my pregnancy cause birth defects?

Very little research has been done on etanercept use during pregnancy. In a survey sent to rheumatologists, the doctors reported no increase in birth defects or miscarriage rates 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. Two studies looking at 25 and 100 women taking etanercept in the first trimester did not find an increased risk for a pattern of birth defects. There have been a few other reports of both normal and abnormal outcomes after women took etanercept during pregnancy.

One 2009 paper reviewed birth defects reported in babies born to mothers who used a TNF inhibitor. The authors suggested that these medications might cause a pattern of birth defects known as VACTERL association (Vertebral, Anal, Tracheal-Esophageal, and Renal birth defects). However, only one case of VACTERL association was found in this series of birth defect reports. Therefore, this review does not support the conclusion that TNF inhibitors cause any increased risk for a pattern of birth defects.

In summary, small studies looking at etanercept use during pregnancy have not shown an increased risk for a pattern of birth defects. However, results from more studies are

needed in order to determine if etanercept is safe to use during pregnancy.

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

A study found that women taking etanercept during pregnancy were more likely to deliver prematurely and have lower birth weight babies than women without rheumatoid arthritis. However, this study also found that these risks were increased for women with rheumatoid arthritis who did not take a TNF inhibitor during pregnancy. Therefore, it may be that the autoimmune condition or use of another medication besides etanercept increased the risk for having a premature or low birth weight baby.

Can I take etanercept while breastfeeding?

There are no studies looking at women who breastfeed while taking etanercept. Because etanercept is a very large protein, it is not likely that very much of the medication would be able to pass into breast milk. In addition, 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 immature digestive systems may be able to absorb more of the medication through breast milk. Be sure to discuss options concerning breastfeeding with your health care provider.

What if the father of the baby takes etanercept?

There are no studies looking at possible risks to a pregnancy when the father takes etanercept. In general, exposure of the father is unlikely to increase the risk to a pregnancy because, unlike the mother, the father does not share a blood connection with the developing baby. For more information, please see the

OTIS fact sheet about Paternal Exposures at <http://otispregnancy.org/pdf/paternal.pdf>.

OTIS 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.

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If you have questions about the information on this fact sheet or other exposures during pregnancy, call OTIS at 1-866-626-6847.