Evolocumab (Repatha®)

This sheet talks about exposure to evolocumab in a pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is evolocumab?
Evolocumab is a prescription medication given by injection (a shot just under the skin). Evolocumab is used, with other medication and lifestyle changes, to lower the levels of “bad” cholesterol known as low-density lipoprotein or LDL cholesterol. It is used to treat a specific type of inherited high cholesterol called familial hypercholesterolemia (FH) and for people with established atherosclerotic cardiovascular disease (ASCVD). Evolocumab is made up of an antibody (blood protein) so it is called a biologic medicine. It is sold under the brand name Repatha®.

How long does evolocumab stay in my system? Should I stop taking it before getting pregnant?
Individuals break down medication at different rates. On average, it can take about 12 weeks (or 3 months) after taking the last dose of evolocumab for nearly all of the medication to be gone from the body. Talk with your healthcare provider before you stop taking this medication. For more information about high cholesterol in pregnancy, please see our fact sheet at https://mothertobaby.org/fact-sheets/high-cholesterol/.

Will taking evolocumab make it harder for me to get pregnant?
Studies have not been done to see if taking evolocumab affects a woman’s ability to become pregnant.

Does taking evolocumab cause an increased risk for miscarriage?
Miscarriage can occur in any pregnancy. Studies have not been done to see if taking evolocumab increases the chance for miscarriage in women.

Can taking evolocumab while pregnant cause birth defects?
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. It is not known if evolocumab can increase the chance for birth defects. Studies on pregnant women have not been done. Animal studies done by the manufacturer have not suggested the medication will increase the chance for birth defects. While this is reassuring, without information about evolocumab use in human pregnancy the effect to the developing baby is not known. Based on what is known about the other antibody medications, very little of the medication would be expected to reach the developing baby in the first trimester. For more information about the critical periods of development, please see our fact sheet at: https://mothertobaby.org/fact-sheets/critical-periods-development/pdf/.

Can taking evolocumab during the second or third trimester cause other pregnancy complications?
This is not known. As the pregnancy continues past the first trimester, more of the medication is expected to reach the pregnancy. At this time, there are no studies on pregnancy complications. Therefore, it is not known if there is or is not an increased chance of a pregnancy complications. There are also no studies looking at the baby’s immune function.

Does taking evolocumab during pregnancy cause long-term problems in behavior or learning for the baby?
At this time, there are no studies on the possible long-term effects of evolocumab on the developing baby. Therefore, it is not known if there is or is not an increased chance of learning problems.
Can I take evolocumab while breastfeeding?

Evolocumab has not been studied for use during breastfeeding. Because it is a very large protein, it is not likely that very much of the medication would be able to pass into breast milk, but studies are needed to confirm this. Evolocumab is not thought to be well absorbed by the stomach, so any of the medication that gets into breast milk would be unlikely to enter the baby’s blood system from their stomach. Premature babies (born before 37 weeks of pregnancy) have digestive systems that are not fully developed, which could allow more of the medication to be absorbed from the breast milk. Talk to your healthcare provider about all of your breastfeeding questions.

If a man takes evolocumab could it affect his fertility (ability to get partner pregnant) or increase the chance of birth defects?

There are no studies looking at possible effects to a pregnancy when a man takes evolocumab. In general, exposures that men have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet on Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/.

MotherToBaby is currently conducting a study looking at evolocumab and other medications used to treat high cholesterol 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/.

References: