Evolocumab (Repatha®)

This sheet is 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 low-density lipoprotein (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 medication. It is sold under the brand name Repatha®.

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 this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy. For more information about high cholesterol in pregnancy, please see our fact sheet at https://mothertobaby.org/fact-sheets/high-cholesterol/.

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

People eliminate medication at different rates. In healthy adults, it takes about 12 weeks (or 3 months), on average, for most of the evolocumab to be gone from the body.

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

It is not known if evolocumab can make it harder to get pregnant.

Does taking evolocumab increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. Studies have not been done to see if evolocumab increases the chance for miscarriage.

Does taking evolocumab 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. It is not known if evolocumab increases the chance for birth defects above the background risk. Animal studies done by the manufacturer have not suggested the medication will increase the chance for birth defects. Based on what is known about 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/.

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

Studies have not been done to see if evolocumab increases the chance for pregnancy related problems such as preterm delivery (birth before 37 weeks of pregnancy) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth).

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

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

Breastfeeding while taking evolocumab:

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. 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. Babies born before 37 weeks of pregnancy

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February 1, 2021

page 1 of 2
have digestive systems that are not fully developed, which could allow more of the medication to be absorbed from the breast milk. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

**If a male takes evolocumab, could it affect 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 male takes evolocumab. In general, exposures that fathers or sperm donors have are unlikely to increase the 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.