Evolocumab (Repatha®)

This sheet is about exposure to evolocumab in 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 that has been used to lower the levels of low-density lipoprotein (LDL) cholesterol. It has been used to treat a type of inherited high cholesterol called familial hypercholesterolemia (FH) and a type of heart disease called 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 women 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. 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 getting pregnant. How long does the drug stay in my body?

People eliminate medication at different rates. In healthy non-pregnant adults, it takes up to 102 days (or about 14 and a ½ weeks), 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?

Studies have not been done in humans to see if evolocumab can make it harder to get pregnant. Information from animal studies does not suggest that taking evolocumab in pregnancy can make it harder to get pregnant.

Does taking evolocumab increase the chance for miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not been done to see if evolocumab can increase the chance of miscarriage.

Does taking evolocumab increase the chance of birth defects?

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at research studies to try to understand if an exposure, like evolocumab, might increase the chance of birth defects in a pregnancy.

Studies have not been done in humans to see if evolocumab can increase the chance of birth defects. Information from animal studies done by the manufacturer does not suggest that taking evolocumab in pregnancy increases the chance of birth defects. Based on what is known about other antibody medications, very little of the medication would be expected to reach the developing fetus in the first trimester.

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

Studies have not been done to see if evolocumab can increase the chance of pregnancy-related problems such as preterm delivery (birth before week 37) 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 increase the chance of behavior or learning issues for the child.

Breastfeeding while taking evolocumab:

Evolocumab has not been studied for use during breastfeeding. This medication is a very large protein, so it is not likely that much of the medication passes into breast milk. Evolocumab is not well absorbed by the stomach, so any

medication that passes into breast milk would be unlikely to enter the baby's blood.

Due to the lack of studies, it has been suggested that evolocumab be used with caution while breastfeeding, especially with a newborn or an infant born preterm. However, the benefit of using evolocumab, along with the benefits of breastfeeding your child, may outweigh possible risks. Your healthcare providers can talk with you about using evolocumab and what treatment is best for you. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes evolocumab, could it affect fertility or increase the chance of birth defects?

Studies have not been done in humans to see if evolocumab could affect a man's fertility (ability to get a woman pregnant) or increase the chance of birth defects. Information from animal studies done by the manufacturer does not suggest that taking evolocumab would affect male fertility. In general, exposures that men 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.

MotherToBaby is currently conducting a study looking at evolocumab in pregnancy. If you are interested in learning more about this study, please call 1-877-311-8972 or visit https://mothertobaby.org/join-study/.

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