Alirocumab (Praluent®)

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

What is alirocumab?
Alirocumab is prescription medication given by injection (a shot just under the skin). It is sold under the brand name Praluent®. Alirocumab is used, with other medicines 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). Alirocumab is made up of an antibody (blood protein) so it is called a biologic medicine.

How long does alirocumab stay in the body? Should I stop taking it before getting pregnant?
Individuals remove medication from their bodies medicines at different rates. On average, it can take about 14 weeks (or a little over 3 months) after taking the last dose of alirocumab for nearly all of this medication to be gone from the body. Talk to 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 alirocumab make it harder for me to get pregnant?
Studies have not been done to see if taking alirocumab affects a woman’s ability to become pregnant.

Does taking alirocumab increase the chance for a miscarriage?
Miscarriage can occur in any pregnancy. Studies on pregnant women have not been done to see if there is any increase in miscarriage while taking alirocumab in early pregnancy.

Can taking alirocumab 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 alirocumab 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 alirocumab 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 alirocumab during the second or third trimester cause other pregnancy complications?
As the pregnancy continues past the first trimester, more of the medication is expected to reach the uterus (organ where baby develops in 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 alirocumab during pregnancy cause long-term problems in behavior or learning for the baby?
This is not known. At this time, there are no studies on the possible long-term effects of alirocumab on the developing baby.
Can I take alirocumab while breastfeeding?

Alirocumab has not been studied for use during breastfeeding. Because it is a very large protein, it is likely that little medication would be able to pass into breast milk. Also, alirocumab is not thought to be well absorbed by the gut, so any of the medication that gets into breastmilk would not be likely to enter the baby’s system. Premature babies (born before 37 weeks of pregnancy) have digestive systems that are not fully developed and may be able to absorb more of the medication through breast milk. Talk to your healthcare provider about all your breastfeeding questions.

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

There are no studies looking at possible effect to a pregnancy when a man takes alirocumab. 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 and Pregnancy at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/.

MotherToBaby is currently conducting a study looking at alirocumab 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/.

Selected References: