Alirocumab (Praluent®)

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

What is alirocumab?

Alirocumab is prescription medication given by injection (a shot just under the skin). 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. A brand name for alirocumab is Praluent®.

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

Studies have not been done to see if taking alirocumab could make it harder to become pregnant.

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

Individuals remove medication from their bodies 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/.

Does taking alirocumab increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. There are no published studies on the use of alirocumab and miscarriage. It is not known if alirocumab increases the chance for miscarriage.

Does taking alirocumab 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. There are no published studies on the use of alirocumab in human pregnancies. Animal research did not suggest that alirocumab would 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.

Could taking alirocumab cause other pregnancy complications?

As the pregnancy continues past the first trimester, more of the medication is likely to reach the uterus (organ where baby develops in pregnancy). However, since there are no published human studies on alirocumab and pregnancy, it is not known if alirocumab can cause other pregnancy complications.

Does taking alirocumab in pregnancy cause long-term problems in behavior or learning for the baby?

There are no published studies on the use of alirocumab. It is not known if alirocumab can cause behavior or learning issues.

Can I breastfeed while taking alirocumab?

Alirocumab has not been studied for use during breastfeeding. Because it is a very large protein, it is not likely that the medication would be able to pass into breast milk in a large amount. 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), and babies under 2 months of age, have digestive systems that are not fully developed and may be able to absorb more of the medication through breast milk. Be sure to talk to your healthcare provider about all your breastfeeding questions.

I take alirocumab. Can it make it harder for me to get my partner pregnant or increase the chance of birth defects?
There are no studies looking at possible effects to a pregnancy when the father or sperm donor takes alirocumab. 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.