



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Alirocumab (Praluent®)

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. This sheet talks about whether exposure to alirocumab may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care 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 break down 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 the medicine to be gone from the body. It is recommended that you talk to your health care provider before you stop taking any medication. For more information about high cholesterol in pregnancy, please see our fact sheet at <https://mothertobaby.org/fact-sheets/high-cholesterol/pdf/>.

Will taking alirocumab make it harder for me to get pregnant?

Studies on women have not been done to see if there is any effect on a woman’s ability to become pregnant while taking alirocumab.

Does taking alirocumab cause an increased risk for miscarriage?

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?

It is not known if alirocumab can cause 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 risk to the developing baby is unknown. 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 cause other pregnancy complications?

Human studies looking at pregnancy complications or the baby’s immune function have not been done.

Can I take alirocumab while breastfeeding?

Alirocumab 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. 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. Be sure to talk to your health care provider about all your

choices for breastfeeding.

What if the father of the baby takes alirocumab?

There are no studies looking at possible risks to a pregnancy when the father takes alirocumab. In general, exposures that fathers 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 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/>.

References:

- Praluent ® Prescribing Information. Available online at <https://products.sanofi.us/praluent/praluent.pdf>. Accessed November 7, 2016.

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