



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

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

For more information about us or to find a service in your area,
call **(866) 626-6847**. Visit us online at **www.MotherToBaby.org**.

Find us! Facebook.com/MotherToBaby or @MotherToBaby on Twitter

Evolocumab (Repatha®)

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 evolocumab 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 evolocumab?

Evolocumab is a prescription medication used to lower the levels of “bad” cholesterol (called low-density lipoprotein or LDL) in the body. People usually take evolocumab along with other cholesterol lowering medication and while trying to make diet and lifestyle changes. It is prescribed for people with familial hypercholesterolemia, a hereditary (genetic) condition of high cholesterol and for people with atherosclerotic cardiovascular disease (ASCVD) who need additional LDL cholesterol lowering. Evolocumab is a human monoclonal antibody (a blood protein) so it is called a ‘biologic medicine’.

Evolocumab is taken by an injection (a shot just under the skin) every 2-4 weeks. It is sold under the brand name Repatha®.

Evolocumab is often used along with other medications called ‘statins’. For more information about the use of different statin medications in pregnancy, please see the MotherToBaby fact sheet on statins at <https://mothertobaby.org/fact-sheets/statins-pregnancy/pdf/>.

How long does evolocumab stay in my system? Should I stop taking it before getting pregnant?

Evolocumab is a long acting medication with a half-life of 11 to 17 days. This means that it may remain in your body for up to three months after the last dose.

You should talk to your health care provider before you stop taking any medication. If you have familial hypercholesterolemia, it is important that you talk with your healthcare provider about your options, weighing the risks and benefits of treatment or no treatment. For more information about high cholesterol in pregnancy, please see the MotherToBaby fact sheet on High Cholesterol at <https://mothertobaby.org/fact-sheets/high-cholesterol/pdf/>.

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

Studies have not been done to see if taking evolocumab affects a woman’s ability to become pregnant.

Does taking evolocumab cause an increased risk for miscarriage?

Studies have not been done to see if taking evolocumab increases the chance for miscarriage.

Can taking evolocumab while pregnant cause birth defects?

It is not known if evolocumab can cause birth defects. There are no human studies looking at exposure to evolocumab during pregnancy. Studies looking at the possible effect on human pregnancy are needed.

Animal studies done by the manufacturer did not show an increase in birth defects with exposure to evolocumab. It is thought that because evolocumab is an antibody, transfer of the medication to the baby may be low in early pregnancy, when many of the organs are forming, but studies are needed to confirm this.

Can taking evolocumab cause other pregnancy complications?

It is not known if evolocumab can cause pregnancy complications. There are no human studies looking at exposure to evolocumab during pregnancy. Studies looking at the possible effect on human pregnancy are needed.

Can I take evolocumab while breastfeeding?

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, but 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. Premature babies (born before 37 weeks of pregnancy) 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 health care provider about all your breastfeeding questions.

What if the father of the baby takes evolocumab?

There are no studies looking at possible risks to a pregnancy when the father takes evolocumab. 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 evolocumab 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:

- Repatha® Prescribing Information. Available online at http://pi.amgen.com/united_states/repatha/repatha_pi_hcp_english.pdf. Accessed November 6, 2016.

September, 2017