Copolymer 1 (Copaxone®)

This sheet talks about exposure to Copolymer 1 (Glatiramer acetate; Glatiramer) in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is Copolymer 1?
Copolymer 1, also known as Cop-I, Glatiramer acetate or Glatiramer, is a disease modifying therapy (DMT) used to treat relapsing-remitting Multiple Sclerosis (MS). Multiple Sclerosis is a condition that affects the nerves in someone’s brain and spinal cord. For more information about Multiple Sclerosis please see the MotherToBaby fact sheet at https://mothertobaby.org/fact-sheets/multiple-sclerosis/pdf/. Copolymer 1 given to patients via an injection into the body. It is sold under the brand name Copaxone®.

I take Copolymer 1. Can it make it harder for me to get pregnant?
Studies on women have not yet been done to see if Copolymer 1 could make it harder for a woman to get pregnant.

I just found out I am pregnant. Should I stop taking Copolymer 1?
Talk with your healthcare provider before making any changes to your medication. There has been no data showing that Copolymer 1 increases chance for miscarriage, birth defects, or adverse pregnancy outcomes. There is also no official recommendation on continued use of this medication during pregnancy. Your healthcare provider can talk with you about the risks and benefits of continuing Copolymer 1 during pregnancy.

Does taking Copolymer 1 increase the chance for miscarriage?
Miscarriage can occur in any pregnancy. Miscarriage has been reported in a couple hundred cases when a mother is taking Copolymer 1. However, there is no data showing an increased chance for miscarriage compared to the general population, or in women who are not taking Copolymer 1.

Does taking Copolymer 1 increase the chance of having a baby with a birth defect?
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. There is limited information about whether Copolymer 1 can increase the chance of birth defects. One large study with over 5,000 pregnancies exposed to Copolymer 1 did not show any increased chance of birth defects. Other studies have shown a possible increased chance. Some of the birth defects described include heart defects, gastrointestinal tract defects, clubfoot, hip dysplasia, and limb abnormalities. No specific pattern of birth defects has been found.

Other pregnancy complications such as stillbirth, intrauterine death/fetal demise, ectopic pregnancy (a fertilized egg that implants outside of the uterus) and molar pregnancy (an abnormal growth inside the uterus that will not become a viable pregnancy) have been reported. These outcomes were reported in less than 1 in 50 pregnancies exposed to Copolymer 1.

Can I breastfeed my baby if I am taking Copolymer 1?
There is limited information about the effects of Copolymer 1 on breastfeeding and effects on the baby. Copolymer 1 is not expected to pass into breast milk. One small study looking at women who breastfed while taking Copolymer 1 reported one infant who had a delay in language development. No other negative effects were described in the rest of the infants in the study. If you are concerned about any symptoms that the baby has, contact the child’s healthcare provider. Be sure to talk to your health care provider about all of your breastfeeding questions.

**What if the baby’s father takes Copolymer 1?**

There have only been a few studies of pregnancy outcomes when a father is taking Copolymer 1. There is no significant or clear evidence that a father taking Copolymer 1 could increase the chance of issues such as low birthweight, miscarriage, or birth defects. In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/.

**Selected References**