



OnabotulinumtoxinA (Botox®)

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 onabotulinumtoxinA 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 professional.

What is onabotulinumtoxinA (botulinum toxin type A)?

OnabotulinumtoxinA has also been called botulinum toxin type A. It is injected into the skin or muscle to treat migraine headaches, excessive sweating, muscle spasms or stiffness, eye muscle conditions (such as crossed eyes), eyelid twitching, and urinary leakage. It is also used cosmetically to reduce the look of wrinkles. Some brand names include Botox® or Botox Cosmetic®.

What is the difference between onabotulinumtoxinA and botulism?

OnabotulinumtoxinA is a germ-free medical treatment made from the purified toxin of a bacterium called *Clostridium botulinum*. This bacterium causes a rare illness called botulism. Botulism is most commonly caused by eating food contaminated with bacterium and its toxin. Botulism bacteria is most common in foods that are not properly preserved, like home canned foods, fermented foods (i.e. sauerkraut and pickled foods), or dented canned foods. The bacteria are killed by heating foods for longer than 5 minutes at greater than 185°F (85°C). People with botulism can have weakness, vision problems, difficulty swallowing, dry mouth, breathing problems, and trouble speaking. In some cases, it can be fatal. Botulism is not contagious.

Does onabotulinumtoxinA get into my bloodstream or cross the placenta?

Not likely. Studies have shown that when injected properly and at the right dose, onabotulinumtoxinA does not usually enter the bloodstream. If it is not in a mother's bloodstream, it cannot cross the placenta. Even if onabotulinumtoxinA did reach the mother's blood stream, the toxin molecule is large and is therefore unlikely to cross the placenta and reach the baby.

Some information that supports this includes one case where a pregnant woman had a botulism infection (was not treatment with onabotulinumtoxinA injection). No botulism was found in her baby's blood after delivery. There are other cases where pregnant women have had botulism and no effects from the botulism were seen in the unborn babies. In one case, even when the mother was temporarily paralyzed from botulism, there was no decrease in fetal movement.

Can having onabotulinumtoxinA treatments make it more difficult to get pregnant?

Not likely. There are no published studies on onabotulinumtoxinA use during pregnancy. Because it does not appear to get into the bloodstream, it is not expected to affect fertility.

Can using onabotulinumtoxinA during pregnancy increase the chance for miscarriage?

Probably not. Currently, there are no published studies on OnabotulinumtoxinA use and miscarriage. Because it does not appear to get into the bloodstream, it is not expected to increase the chance for miscarriage.

Can using onabotulinumtoxinA treatments during pregnancy increase the chance for birth defects?

Probably not. There are no published studies on onabotulinumtoxinA use during pregnancy and other reports are limited. A report from the manufacturer, which included 137 pregnancies exposed either during pregnancy or a few months before getting pregnant, did not find a pattern of birth defects or an increased chance of birth defects.

Can I have onabotulinumtoxinA treatments while breastfeeding?

Probably. No studies on breastfeeding while using onabotulinumtoxinA are available. However, because onabotulinumtoxinA injections are not thought to get into the bloodstream, it would be unlikely to be able to enter the breast milk. Therefore, the risk to an infant is thought to be very low. Be sure to talk to your health care provider about all your breastfeeding questions.

What if the father of the baby uses onabotulinumtoxinA?

An increased risk of birth defects or pregnancy complications is not expected when the father of the baby uses onabotulinumtoxinA. 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 and Pregnancy at

<http://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

Selected References:

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