

OnabotulinumtoxinA (Botox®)

This sheet is about exposure to onabotulinumtoxinA in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

What is onabotulinumtoxinA?

OnabotulinumtoxinA (formerly called botulinum toxin type A) has been used 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. It is injected into the skin or muscle. Some brand names include Botox® or Botox Cosmetic® and Oculinum®.

There are also other forms of botulinum toxin that are used for cosmetic and medical reasons. Some brands names are Dysport®, Xeomin®. These products have not been studied for use in pregnancy. It is not known how the information about using these products might be the same or different from the information about using onabotulinumtoxinA.

Sometimes when women find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

Is onabotulinumtoxinA related to botulism?

OnabotulinumtoxinA is a germ-free medical treatment made from the purified toxin of a bacterium called **Clostridium botulinum** (**C. botulinum**). **C. botulinum** can cause a rare illness called botulism. People get botulism most commonly by eating food contaminated with **C. botulinum**. Botulism bacteria are 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, trouble swallowing, dry mouth, breathing problems, and trouble speaking. In some cases, it can be fatal. Botulism is not contagious.

I get onabotulinumtoxinA treatments, but I would like to stop before getting pregnant. How long does the drug stay in my body?

People eliminate medication at different rates. It has been suggested that onabotulinumtoxinA stays in a person's system for about 4-6 months. Your healthcare provider can talk with you about when stopping your treatments may be recommended.

I get onabotulinumtoxinA treatments. Can they make it harder for me to get pregnant? It is not known if onabotulinumtoxinA can make it harder to get pregnant. Because it does not appear to get into the bloodstream, it is not expected to affect the ability to get pregnant.

Does using onabotulinumtoxinA increase the chance for miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. A report from the manufacturer did not find an increased chance for miscarriage. Other studies have not been done to see if onabotulinumtoxinA increases the chance for miscarriage. Because it does not appear to get into the bloodstream, it is not expected to increase the chance for miscarriage.

Does using onabotulinumtoxinA 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 onabotulinumtoxinA use during pregnancy. A report from the manufacturer, which included 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. Because it does not appear to get into the bloodstream, it is not expected to increase the chance for birth defects.



Does taking onabotulinumtoxinA in pregnancy increase the chance of other pregnancy-related problems?

Studies have not been done to see if onabotulinumtoxinA increases the chance for pregnancy-related problems such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth). A report from the manufacturer did not find a higher chance for preterm delivery. Because it does not appear to get into the bloodstream, it is not expected to increase the chance for pregnancy-related problems.

Does taking onabotulinumtoxinA in pregnancy affect future behavior or learning for the child?

Studies have not been done to see if onabotulinumtoxinA can cause behavior or learning issues for the child. Because it does not appear to get into the bloodstream, it is not expected to increase the chance for effects on behavior or learning in the child.

Breastfeeding while taking onabotulinumtoxinA:

Studies on breastfeeding while using onabotulinumtoxinA have not been done. However, because onabotulinumtoxinA injections are not thought to get into the bloodstream, it would be unlikely to enter the breast milk. That means risks to an infant are thought to be low. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man uses onabotulinumtoxinA, could it affect fertility or increase the chance of birth defects?

Studies have not been done to see if onabotulinumtoxinA could affect fertility (ability to get a woman pregnant) or increase the chance of birth defects above the background risk. In general, exposures that men 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.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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