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## Isotretinoin (Accutane®) and Pregnancy

This sheet talks about the risks that exposure to isotretinoin can have during pregnancy. With each pregnancy, all women have a 3% to 5% chance of having a baby with a birth defect. This information should not take the place of medical care and advice from your health care provider.

### **What is isotretinoin?**

Isotretinoin is a prescription medication taken by mouth to treat severe disfiguring cystic acne that has not responded to other treatments. Isotretinoin is a man-made form of Vitamin A. It is sold under brand names such as Accutane®, Amnesteem®, Claravis®, and Sotret®.

### **How long does isotretinoin stay in the body? How long after a woman stops taking isotretinoin should she wait to become pregnant?**

The time it takes isotretinoin to be cleared from the blood varies. Usually, isotretinoin is no longer found in a woman's blood 4-5 days after the last dose. Most of its by-products should be gone within 10 days after the last dose. It is recommended that a woman wait one month after stopping isotretinoin before trying to become pregnant.

### **Can isotretinoin make it more difficult to get pregnant?**

There have been reports of irregular menstrual periods in some women taking isotretinoin. There are no reports of problems getting pregnant while taking isotretinoin. **Women who are trying to become pregnant should not be taking isotretinoin!**

### **Does exposure to isotretinoin cause an increased risk for miscarriage or infant death?**

YES. The risk for having a miscarriage may be as high as 40% when a woman takes isotretinoin in early pregnancy.

### **Can taking isotretinoin during pregnancy cause birth defects?**

YES. Isotretinoin causes a pattern of birth defects in more than 35% of infants whose mothers take the drug during pregnancy. Most of the infants

with birth defects will have small or absent ears, hearing and eyesight problems. Some will have a small jaw, small head, cleft palate and some will be born with a small or missing thymus gland. Life threatening heart defects and fluid around the brain are seen in almost half of the exposed infants.

### **Will taking isotretinoin have an effect on a baby's behavior and development?**

YES. Many of the exposed children will have moderate to severe mental retardation. These difficulties do not get noticed at birth, but are discovered in childhood. The long-term effects on any exposed child are still unknown.

### **If a woman gets pregnant while taking isotretinoin, what should she do?**

**Stop taking the medicine right away!** As soon as possible, call the doctor who prescribed the isotretinoin and the doctor who will be taking care of you during your pregnancy. Your doctors can tell you what the risks are and testing that may be done. A special ultrasound done in the second trimester of pregnancy may be able to see if a birth defect has been caused by exposure to isotretinoin. Ultrasound can detect many birth defects but it cannot tell if a child may have learning or developmental problems.

### **Can a woman ever safely use isotretinoin?**

YES. Isotretinoin can be prescribed under a special program called iPLEDGE™. Women MUST adhere to all requirements of the iPLEDGE program. Following are a few of the requirements:

- ❑ Women must be able to understand that severe birth defects can occur with use of isotretinoin.
- ❑ Women must receive and be able to understand safety information about isotretinoin and the iPLEDGE requirements.

- ❑ Women must sign an Informed Consent Form that contains warnings about the risks of using isotretinoin.
  - ❑ Women must not be pregnant or be breastfeeding.
  - ❑ Women must have two (2) negative pregnancy tests before starting isotretinoin.
  - ❑ Women must have a pregnancy test every month during treatment, and a negative test a month after treatment.
  - ❑ Women must use two (2) different forms of birth control at all times (unless woman agrees not to have sex) starting one (1) month before treatment continuing during treatment, and for one (1) month after treatment.
  - ❑ Women must fill their prescription within 7 days after the doctor visit.
  - ❑ Women must agree to see their doctor every month during treatment for a health check and to get a new prescription.
- For more information about the iPLEDGE program call 1-866-495-0654 or visit the iPLEDGE website <https://www.ipledgeprogram.com>.

OTIS recommends that women who are not sexually active still talk to their health care provider about using a safe and effective birth control method because almost 50% of all pregnancies are unplanned or unintended.

### ***Can isotretinoin be taken while breastfeeding?***

There have been no studies looking at taking isotretinoin during breastfeeding. It is not known if isotretinoin can get into breast milk but other similar medications can. We do not know what effect exposure to isotretinoin through the breast milk can have on a nursing infant. Until more is known, women who are breastfeeding should not take isotretinoin.

### ***What if the father of the baby takes isotretinoin?***

Isotretinoin does not appear to affect sperm count or movement. There have been a few reports of ejaculatory failure in men taking isotretinoin, but there have been no reports of isotretinoin causing infertility in men. There are no studies looking at risks for birth defects when the father takes isotretinoin. In general, medications a father takes do not increase the risk to a pregnancy because the father does not share a blood connection with a developing baby.

### ***Isotretinoin is a man-made Vitamin A. Are there other Vitamin A-related medicines that women should avoid prior to or during pregnancy?***

YES. Etretinate (Tegison<sup>®</sup>), Acitretin (Soriatane<sup>®</sup>) and high dose Vitamin A (more than 20,000 IU per day) are medications used to treat skin problems. They should **never** be used by women of childbearing age and can cause birth defects similar to isotretinoin.

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*If you have questions about the information on this fact sheet or other exposures during pregnancy, call OTIS at 1-866-626-6847.*