Isotretinoin (Accutane®)

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

What is isotretinoin?

Isotretinoin is a prescription medication taken by mouth (orally) that has been used to treat severe cystic acne when other treatments have not worked. Isotretinoin is a type of retinoid made from vitamin A. Brand names include Accutane®, Absorica®, Amnesteem®, Claravis®, Epuris®, Clarus®, Myorisan®, Sotret®, and Zenatane®.

The product label for isotretinoin recommends not using this medication while pregnant or breastfeeding. If you are taking isotretinoin and find out you are pregnant, stop taking the medication and contact your healthcare provider immediately. If you are taking isotretinoin and want to get pregnant, talk with your healthcare provider.

Can I get a prescription for isotretinoin?

Isotretinoin can be prescribed under a special program called iPLEDGE® Risk Evaluation and Mitigation Strategy (REMS). All requirements of the program must be followed to get prescriptions for isotretinoin.
Some requirements are:

- Must talk with your healthcare provider about isotretinoin and the iPLEDGE® REMS program.
- Must be able to understand that severe birth defects can happen with use of isotretinoin.
- Must receive and be able to understand safety information about isotretinoin and the iPLEDGE® REMS program.
- Must be enrolled by your healthcare provider in the iPLEDGE® REMS program for 30 days before your first prescription.
- Must read, understand, and sign a consent form that contains warnings about the risks of using isotretinoin.
- Must correctly answer comprehensive questions on the iPLEDGE® REMS program website.
- Must not be pregnant, trying to get pregnant, or breastfeeding.
- Must have 2 negative pregnancy tests before starting isotretinoin.
- Must have a pregnancy test every month during treatment.
- Must have a negative pregnancy test before each monthly prescription.
- Must always use 2 different forms of birth control starting 1 month before treatment. Continue using 2 forms during treatment, and for 1 month after treatment.
- Must agree to see your healthcare provider every month during treatment for a health check and to get a new prescription.
- Must not share medication with anyone.
- Must not donate blood during treatment and for 1 month after treatment.
- For more information about the iPLEDGE program call 1-866-495-0654 or visit the iPLEDGE website at https://www.ipledgeprogram.com.

Even if you are not sexually active or planning a pregnancy, if you use or want to use isotretinoin, it is recommended to talk to your healthcare provider. Using effective birth control methods is important because about 50% (1 out of 2) of pregnancies are unplanned.

I am taking isotretinoin, but I would like to stop taking it before getting pregnant. How

long does the drug stay in my body?
The time it takes the body to metabolize (process) medication is not the same for everyone. In healthy non-pregnant adults, it takes up to 6 days, on average, for most of the isotretinoin to be gone from the body.

It is recommended to wait one month after stopping isotretinoin before trying to get pregnant.

I take isotretinoin. Can it make it harder for me to get pregnant?
Some women taking isotretinoin have reported changes in their menstrual cycle (periods), but there are no reports that it makes it harder to get pregnant. However, it is not recommended to get pregnant while using isotretinoin.

I just found out I am pregnant. Should I stop taking isotretinoin?
Yes, it is recommended that you stop taking isotretinoin right away if you find out you are pregnant. As soon as possible, call the healthcare provider who prescribed the isotretinoin and the healthcare provider who will be taking care of you during pregnancy. Isotretinoin increases the chance of birth defects.

Does taking isotretinoin increase the chance of miscarriage?
Miscarriage is common and can occur in any pregnancy for many different reasons. Taking isotretinoin can increase the chance of miscarriage. The chance of having a miscarriage can be as high as 40% when isotretinoin is used in early pregnancy.

Does taking isotretinoin increase the chance of birth defects?
Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at research studies to try to understand if an exposure, like isotretinoin, might increase the chance of birth defects in a pregnancy.

Isotretinoin can cause birth defects in 35% or more of infants who are exposed during pregnancy. There is an increased chance of birth defects even if the medication has been taken for a short time. Most of the infants with birth defects will have small or absent ears and hearing and eyesight problems. Other issues that have been reported include heart defects, fluid around the brain, small jaw, small head, cleft palate (opening in the roof of the mouth), and/or missing thymus gland (a gland that makes hormones). Not every pregnancy exposed to isotretinoin will have birth defects. However, it is recommended to avoid any isotretinoin use in pregnancy.

Does taking isotretinoin in pregnancy increase the chance of other pregnancy-related problems?
The use of isotretinoin in pregnancy can increase the chance of preterm delivery (birth before week 37) and low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth).

Does taking isotretinoin in pregnancy affect future behavior or learning for the child?
Children exposed to isotretinoin during pregnancy may have hearing or vision problems that can affect learning. They may also have behavioral problems or intellectual disability. These issues are not always seen at birth and may appear as the child grows.

What screenings or tests are available to see if my pregnancy has birth defects or other issues?
Prenatal ultrasounds can screen for some birth defects and monitor the growth of the pregnancy. Talk with your healthcare provider about any prenatal screenings or testing that are available to you. There are no tests available during pregnancy that can tell how much effect there could be on future behavior or learning.

Breastfeeding while taking isotretinoin:
No information is available on the use of isotretinoin during breastfeeding. Due to the lack of data, the product label recommends not using this medication while breastfeeding. It is not known what effect, if any, exposure to isotretinoin through breast milk can have on a nursing infant. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

There have been a few reports of erectile dysfunction (trouble getting or keeping an erection) and ejaculatory problems (no semen released) in men taking isotretinoin. Changes in sperm morphology (size and shape) have also been reported. This could affect men's fertility (ability to make healthy sperm). Studies have not been done in men to see if isotretinoin could increase the chance of birth defects. In general, exposures that fathers or sperm donors have are unlikely to increase 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.

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