

# Isotretinoin (Accutane®)

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This sheet is about exposure to isotretinoin 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 isotretinoin?***

Isotretinoin is a prescription medication taken by mouth (orally) to treat severe cystic acne when other treatments have not worked. Isotretinoin is a form of Vitamin A. It has been sold under brand names such as Accutane®, Absorica®, Amnesteem®, Claravis®, Epuris®, Clarus®, Myorisan®, Sotret®, and Zenatane®.

The product label for isotretinoin recommends people who are pregnant do not use this medication. This is because using isotretinoin in pregnancy can lead to birth defects and other pregnancy related problems. If you are taking isotretinoin and find out you are pregnant, stop taking the medication and contact your healthcare provider right away. If you are taking isotretinoin and want to get pregnant, talk with your healthcare provider about your condition and what treatment is best for you.

## ***I take isotretinoin. Can it make it harder for me to get pregnant?***

People who are trying to get pregnant should not be taking isotretinoin. There have been reports of changes in the menstrual cycle (periods) in some people taking isotretinoin. There are no reports of problems getting pregnant while taking isotretinoin.

## ***I am taking isotretinoin, but I would like to stop taking it before pregnancy. How long does it stay in my body?***

People eliminate medication at different rates. In healthy adults, it takes up to 6 days, on average, for most of the isotretinoin to be gone from the body. However, it is recommended that a person wait one month after stopping isotretinoin before trying to get pregnant.

## ***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 your pregnancy. Isotretinoin can cause birth defects. Your healthcare team can talk with you about the risks to your pregnancy and available options.

## ***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?***

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Isotretinoin causes birth defects in up to 35% or more of infants who are exposed during pregnancy. There is a chance of having a baby with a birth defect 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 also been reported include: heart defects, fluid around the brain, small jaw, small head, cleft palate (opening in the roof of the mouth), and being born with a small or missing thymus gland (a gland that makes hormones). While not every pregnancy exposed to isotretinoin will have birth defects, it is recommended to avoid any isotretinoin use in pregnancy.

## ***Does taking isotretinoin in pregnancy increase the chance of other pregnancy-related problems?***

An increased chance for preterm delivery (birth before week 37) has been associated with the use of isotretinoin in pregnancy.

## ***Does taking isotretinoin in pregnancy affect future behavior or learning for the child?***

Children exposed to isotretinoin during pregnancy can have hearing and eyesight problems, which can cause issues with learning. Exposed children can also have moderate to severe behavioral problems and/or intellectual disability. These issues are not usually noticed at birth but are found later as the child grows. Other possible long-term effects on children exposed to isotretinoin during pregnancy are unknown.

***What screenings or tests are available to see if my pregnancy has birth defects or other issues?***

Prenatal ultrasounds can be used to screen for some birth defects. Ultrasound can also be used to 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.

***Can I still get a prescription for isotretinoin?***

Isotretinoin can be prescribed under a special program called iPLEDGE® Risk Evaluation and Mitigation Strategy (REMS). People **MUST** adhere to all requirements of the program to get prescriptions for isotretinoin. The following are some of the requirements:

- Must talk with your healthcare provider about isotretinoin and the iPLEDGE® REMS program.
- Must be able to understand that severe birth defects can occur with use of isotretinoin.
- Must receive and be able to understand safety information about isotretinoin and the iPLEDGE® REMS program requirements.
- Must be enrolled by your healthcare provider in the iPLEDGE® REMS program for 30 days before first prescription.
- Must read, understand, and sign an informed consent form that contains warnings about the risks of using isotretinoin.
- Must correctly answer comprehensive questions in the iPLEDGE® REMS program website.
- Must not be pregnant, trying to get pregnant, or breastfeeding.
- Must have two (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 use two (2) different forms of birth control at all times (unless agrees not to have sex) starting one (1) month before treatment, continue using 2 forms during treatment, and also for one (1) month after treatment.
- Must fill prescription within 7 days after the health care provider visit.
- 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 one (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 that you talk to your healthcare provider. Using effective birth control methods is important because almost 50% of all pregnancies are unplanned or unintended.

***Breastfeeding while taking isotretinoin:***

The product label for isotretinoin recommends people who are breastfeeding not use this medication. There have been no studies looking at the use of isotretinoin during 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 male takes isotretinoin, could it affect fertility or increase the chance of birth defects?***

There have been a few reports of erectile dysfunction (trouble with getting and keeping an erection) and ejaculatory failure (no seminal fluid comes out of the penis) in males taking isotretinoin. This can affect fertility (ability to get partner pregnant). Studies have not been done in males 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/>.

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