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Accutane (Isotretinoin) and Pregnancy

The information below will help you determine if the use of Accutane represents an increased fetal risk. With every pregnancy, all women have a 3 to 5 percent chance to have a baby with a birth defect.

What is Accutane?

Accutane is a prescription medication taken by mouth to treat severe disfiguring cystic acne that has not responded to other treatments. Accutane is a man-made form of Vitamin A. Its generic name is isotretinoin. In 2002 the patent on this product expired allowing other drug companies to make and sell isotretinoin under different trade names.

Can taking Accutane during pregnancy cause birth defects?

YES. A pattern of birth defects occurs in approximately 25-35% of infants of women exposed to Accutane during the first trimester. This pattern includes craniofacial defects (ears, eyes, and bone development), heart defects, and central nervous system defects (brain abnormalities). Occasionally, defects of the thymus gland and limb abnormalities are seen.

Will taking Accutane have an effect on a baby's behavior and development?

Some children exposed to Accutane are mentally retarded, while others have learning difficulties, including problems with attention span, hand-eye coordination, and visual-perceptual and organizational abilities. Many of these difficulties do not get noticed at birth, but are discovered in childhood. The long-term effects on any exposed child are still unknown.

Does exposure to Accutane cause an increased risk for miscarriage or infant death?

YES. There is a significantly increased risk for miscarriage, possibly as high as 50%, with exposure to Accutane. Additionally, a child born with the birth defects known to occur more frequently with Accutane use in pregnancy may be at an increased risk for infant death.

If a woman gets pregnant while taking Accutane, what should she do?

She should stop taking the medication immediately and contact her health care providers (including the prescribing doctor and gynecologist/obstetrician) to discuss her options. Prenatal testing is available to determine if birth defects are present. A detailed ultrasound performed in the second trimester of pregnancy may be able to identify major malformations caused by Accutane exposure. Although ultrasound can detect many birth defects, it is not able to detect all potential fetal problems caused by exposure to Accutane.

Can Accutane make it more difficult to get pregnant?

Menstrual irregularities, which often make getting pregnant more difficult, have been reported in some women treated with isotretinoin. There are, however, no reports of fertility problems following use of Accutane. Women who are trying to become pregnant should not be taking Accutane.

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

The time it takes Accutane to clear from the blood stream varies since some women use higher doses than others and some women may not be using the medication as prescribed. The average half-life (the time it takes to eliminate one half of the drug from the body) is 16-20 hours, but some of its breakdown products have a half-life of 50 hours. Isotretinoin is not detectable in a woman's blood 4-5 days after the last dose, and most of its by-products should be gone within 10 days after the last dose. The manufacturer recommends that a woman use **two** forms of birth control **at the same time** beginning one month prior to starting Accutane through one month after stopping Accutane.

Can a woman ever safely use Accutane?

YES, if she and her physician discuss in detail and adhere to the following guidelines:

1. Women of childbearing age must use **two** reliable forms of birth control **at the same time**. Birth control should start one month prior to filling their Accutane prescription and continue through one month after stopping use of Accutane.
2. Women must be counseled about the possible ways that their chosen birth control methods may fail. The manufacturer of Accutane, Hoffman-LaRoche, will pay for an initial pregnancy test and contraceptive counseling consultation when the prescribing doctor provides a woman with the Accutane referral form.
3. Women must have two **negative** blood or urine pregnancy tests prior to starting Accutane. The second test must be done during the first five days of a menstrual period.
4. Accutane must be started after the second negative pregnancy test.
5. Only a one-month supply of Accutane can be prescribed. For each prescription, a woman and her physician should repeat the guidelines.

Are there other Vitamin A-related medications women should avoid prior to or during pregnancy?

YES. Tegison (etretinate) is another oral medication used to treat severe psoriasis. It should **never** be used by a woman of childbearing age. It may cause birth defects similar to Accutane even when Tegison use has been stopped years before becoming pregnant.

Retin-A (tretinoin) and isotretinoin gels are topical products (applied to the skin) that should be used with caution or avoided in pregnancy. They do not, however, pose the same level of increased risk seen with prenatal Accutane use.

Can Accutane be taken while breastfeeding?

Accutane has not been studied during breastfeeding. It is not known if Accutane can get into breast milk, but it is likely as with other similar medications. Until more is known, women who are breastfeeding should not take Accutane.

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