

Birth Defect Research for Children, inc.

Fact Sheet

Accutane (Isotretinoin)

What is it? Accutane (manufactured by Roche Laboratories) is the trade name for isotretinoin. The manufacturer recommends that this powerful, and very popular, prescription drug only be used in the treatment of severe, recalcitrant, nodular acne, which is unresponsive to conventional therapy, including systemic antibiotics.

How does it work? Accutane decreases the amount of oil produced by the skin's sebaceous (oil) glands. The medicine is most effective when taken with food (preferably, high in fat), which increases the absorption of the drug. It usually requires two months of treatment with Accutane before any visible improvements in the skin are noticed. Typical treatment lasts four to five months generally resulting in the patient being clear of acne for a year or more after the medicine is stopped. Accutane is not a permanent cure for acne, however - One in four patients experiences a reoccurrence of acne two years after stopping the medicine and may require another cycle of drug treatment.

Acute Health Effects: The following are acute side effects of Accutane:
Intestinal and urinary symptoms - including inflammatory bowel disease
Headaches
Rash
Emotional depression, psychiatric disorders and thoughts of suicide
Acute pancreatitis

Chronic Health Effects: Taking Accutane may result in these chronic problems:
Chapped lips
Dry and itching skin
Nosebleeds and unusually dry nostrils
Irritation of eyelids and eyes
Joint and muscle pains
Temporary hair thinning

- Elevation of serum triglycerides
- Hearing impairment
- Increased sensitivity to sunburn
- Corneal opacities
- Decreased night vision
- Hepatotoxicity (elevation of liver enzymes)

Pseudotumor Cerebri: Accutane has been associated with a number of cases of pseudotumor cerebri (benign intracranial hypertension). Among early signs of the disease are papilledema, headache, nausea, vomiting and visual disturbances. Untreated pseudotumor cerebri can lead to blindness. It is important that patients be screened for papilledema prior to starting Accutane treatments.

Reproductive Health Effects: If Accutane is taken during pregnancy it can cause very serious defects to the unborn child. These defects can include:

- Skull abnormality
- Ear abnormality
- Eye abnormality
- Facial dysmorphism
- Central Nervous System (CNS) abnormalities
- Cardiovascular abnormalities
- Thymus gland abnormality
- Parathyroid hormone deficiency
- Mental retardation

Controlling Risk of Exposure: The manufacturer of Accutane and the FDA started a pregnancy-prevention program in 1988 for reproductive-aged women taking the drug. The program includes contraceptive counseling and the requirement that patients must sign a consent form before starting treatment. The consent form includes the following statements and warnings to the patient:

Accutane is a powerful, "last resort" medication for severe acne. You must not take Accutane if you are pregnant or may become pregnant during treatment. If you get pregnant while taking Accutane, your baby will be at high risk for birth defects. If you take Accutane, you must use effective birth control from 1 month before the start of treatment through 1 month after the end of treatment.

You must test negative for pregnancy within 2 weeks before starting Accutane, and you must start Accutane on the second or third day of your menstrual period. You may participate in a program that includes an initial free pregnancy test and birth control counseling session. If you become pregnant, you must immediately stop taking Accutane and see your doctor. You have read and understood the Accutane patient brochure and asked your doctor any questions you had. You are not currently pregnant and do not plan to become pregnant for at least 30 days after you finish taking Accutane. You have been invited to participate in a survey of women being treated with Accutane.

Accutane is stored in the body's fatty tissues, which may be a factor in the drug remaining efficacious in patients up to two years after treatment has stopped. For this reason, the 30-day recommended interval between treatment and being able to initiate a safe pregnancy should be considered the absolute minimum allowable time, and not the ideal.

It is critically important for women not to take Accutane while pregnant, and not to become pregnant while taking it. Women who are, or expect to be, sexually active while taking Accutane must use an effective method of birth control. This usually means oral contraceptive pills and one other additional method of birth control such as condoms for the male partner. Some physicians require their patients to sign a statement that they would consider a pregnancy termination if they became pregnant while taking Accutane.

While there is insufficient evidence available, there is a concern that men taking Accutane may be able to cause birth defects through sexual transmission. For this reason, men being under treatment should use a condom during sexual activity.

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