CENTER FOR DERMATOLOGY, COSMETIC AND LASER SURGERY

2557 Mowry Avenue, Ste 25 Fremont, CA 94538 (510) 797-4111 995 Montague Expy #111 Milpitas, CA 95035 (408) 957-7676

iPledge patient information for Males and Females

What Do All Patients Need To Know?

Prevent Pregnancy and Birth Defects There is a very high chance that babies born to female patients taking isotretinoin will be deformed, born too early, or die before they are born. This can happen even if a female patient takes isotretinoin for only a short time. It may also happen if a pregnant female receives a blood transfusion from someone taking isotretinoin.

Do male patients taking isotretinoin need to worry about birth defects?

Unlike in female patients, there is no pattern of birth defects in babies whose fathers were taking isotretinoin. If you are worried about isotretinoin birth defects from sperm, you can use a male latex condom to help prevent pregnancy. Use a condom each and every time you have intercourse (sex) while you are taking isotretinoin and for 1 month after you stop taking it. **Can isotretinoin affect a male patient's ability to father healthy children?**

Studies on isotretinoin did not show effects on sperm count, how sperm look, or how well they swim and move.

Do Not Donate Blood

Isotretinoin is carried in your blood. There may be enough isotretinoin in your bloodstream to cause birth defects if a pregnant female gets blood from you. You should not donate blood at any time while you are taking isotretinoin or for 1 month after your last dose.

Do Not Share Isotretinoin with Anyone

You should never share medications prescribed to you with anyone else. This is very important for isotretinoin because of the very high chance of birth defects. Obtain Your Prescription

Obtain your isotretinoin

prescriptions only at pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program. The web site, www.ipledgeprogram.com, has a list of registered pharmacies. Once on the web site choose "Find a Participating Pharmacy" in the left navigation. A complete list of FDA-approved isotretinoin products that may be prescribed and dispensed may be found by calling 1-866-495-0654 or via <u>www.ipledgeprogram.com</u>.

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What Do Female Patients Who Can Get Pregnant Need To Know?

DO NOT take isotretinoin if you are pregnant. DO NOT get pregnant before starting isotretinoin, while taking it, and for 1 month after your last dose.

Before you can begin isotretinoin treatment, there is a 30-day wait period where you must be on 2 methods of birth control. Additionally, you need to have 2 negative pregnancy tests. They can be urine or blood tests. You will need to plan with your doctor/prescriber when and where to take your pregnancy tests.

• You take the first test when you decide to take isotretinoin.

• You take the second test during the first 5 days of the menstrual period right before you start isotretinoin. This pregnancy test must be done by an approved lab. The interval between the 2 tests must be at least 19 days.

You must take a pregnancy test every month done by an approved lab during treatment. You also take a pregnancy test after your last dose, and 1 month after your last dose. You will need to plan with your doctor/prescriber when to take your pregnancy test each month.

Have 2 negative pregnancy tests before you start isotretinoin.

Have a negative pregnancy test before you obtain each monthly prescription.

To keep from getting pregnant, you need to use 2 effective methods of birth control together correctly all the time:

- For at least 1 month before you start isotretinoin
- During treatment which usually lasts 4 to 5 months
- For 1 month after your last dose—to continue protection against pregnancy

Any method of birth control can fail. Using 2 methods of birth control together all the time drastically reduces the chance that you will get pregnant.