



## Most Common Reasons Reported for an iPLEDGE Pregnancy By iPLEDGE Prescribers and Patients

**Did not use 2 forms of birth control  
Did not use contraception on date of conception  
Unsuccessful at abstinence**

Analysis of iPLEDGE pregnancy data over the past several years has identified improper contraceptive use during iPLEDGE treatment as the most common reason reported by both iPLEDGE prescribers and their patients who became pregnant during or within 30 days after stopping treatment.

**All female patients of childbearing potential must receive contraception counseling and must fully commit to pregnancy prevention.**

Female patients of childbearing potential are required to enter their contraceptive choices during the interaction with the iPLEDGE system for each prescription window. Birth control pills (BCPs) and male condoms were the most frequent primary and secondary methods of contraception for the women who had iPLEDGE pregnancies over the past few years; these were also the most frequent primary and secondary methods of contraception for the non-pregnant females. Abstinence was the next most frequent method of contraception for the non-pregnant and pregnant females.

The most common reason for an iPLEDGE pregnancy, as reported by the prescriber and the patient, was failure to comply with the iPLEDGE contraceptive requirements (e.g., did not use two forms of birth control, did not use contraception on the date of conception, unsuccessful at abstinence).

One key component of the iPLEDGE program is for the prescriber to either provide contraceptive counseling to all females of childbearing potential or to refer the patient to a contraceptive counselor to provide this information before therapy starts. This counseling is intended to assist the patient in selecting the two forms of contraception that she will use while on therapy that will fit into her lifestyle.

### **YOU ARE THE CRITICAL LINK TO PREVENTING EXPOSED PREGNANCIES**

#### **Contraception Counseling**

The prescriber must ensure that each individual patient receives adequate counseling regarding all her pregnancy prevention options (including abstinence) and that she knows how to select and use two separate, iPLEDGE program-effective forms of contraception that will provide her with the lowest failure rate.

**Abstinence without appropriate contraception is not recommended for patients in the iPLEDGE program who are or have been sexually active.** Abstinence may be appropriate when it is a lifestyle choice (e.g., religious practice) and not just a social circumstance (e.g., not having a current partner). If, after counseling, a sexually active patient chooses abstinence without contraception, it is important that the prescriber reinforces the importance to comply with



the iPLEDGE program contraception requirement and to inform the prescriber if she does not remain abstinent.

The patient must understand the critical responsibility she assumes in electing to undertake therapy with isotretinoin and that any form of birth control, apart from complete abstinence, can fail. All female patients of childbearing potential must read the patient iPLEDGE Program Birth Control Workbook.

**Continually reinforce the message. Active counseling is one of the best tools toward achieving patient compliance.** Counseling about contraception must be repeated on a monthly basis. When counseling patients on contraception, the prescriber should refer to The iPLEDGE Program Prescriber Contraception Counseling Guide, which contains an overview of issues in contraception and the effective forms of contraception in the iPLEDGE program. It is a companion to the patient iPLEDGE Program Birth Control Workbook.

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## SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE<sup>TM</sup>. Under this program, prescribers must be registered and activated with the iPLEDGE program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the skin, pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.



# iPLEDGE™

Committed to Pregnancy Prevention

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Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions at:

- Absorica: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=8d54aab5-3349-4a41-8533-0a566fd7bbaa>
- Amnesteem: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=b2cb63c9-f825-4991-9a2c-6260f1bbcc2c>
- Claravis: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a31fd109-d0fd-4ab9-ba98-a3d64333c18d>
- Myorisan: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=51ff6346-9256-4c01-9f52-417d13f2df05>
- Sotret: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=d5a26c5e-9c3e-4781-8c08-62b91d21a68d>
- Zenatane: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=27b3cf26-f22e-5b70-1c24-009933b7c6ee>