



**iPLEDGE**<sup>®</sup>  
Committed to Pregnancy Prevention

The iPLEDGE REMS



# Pharmacist Guide



This guide is for pharmacists who dispense isotretinoin. It contains resources to help you understand and comply with the iPLEDGE REMS for isotretinoin treatment.

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## What is Isotretinoin?

Isotretinoin is used to treat severe recalcitrant nodular acne. Isotretinoin belongs to a class of drugs known as retinoids, commonly understood to include all natural and synthetic analogues of vitamin A. Treatment with isotretinoin should not be undertaken before conventional treatment has been tried first, including the use of systemic antibiotic therapy, and the patient has been fully counseled about the warnings and precautions in the isotretinoin package insert.

## What is the most important information I should know about isotretinoin?



**Isotretinoin is teratogenic** and must not be used by pregnant patients. Patients should not get pregnant while taking isotretinoin and for 1 month after treatment is discontinued. A patient who gets pregnant during treatment should stop taking isotretinoin and immediately contact the prescriber.

### Birth Defects

There is an extremely high risk that a deformed infant will result if pregnancy occurs while patients who **can** get pregnant are taking isotretinoin in any amount, even for short periods of time. Potentially, any fetus exposed during pregnancy can be affected. Not every fetus exposed to isotretinoin has resulted in a deformed child. However, there are no accurate means of determining which fetus has been affected and which fetus has not been affected.

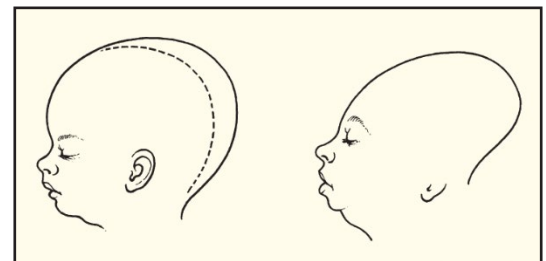
When isotretinoin is taken during pregnancy, it has been associated with fetal malformations, and there is an increased risk for spontaneous abortions and premature birth. **The following human fetal abnormalities have been documented.**

#### External Abnormalities

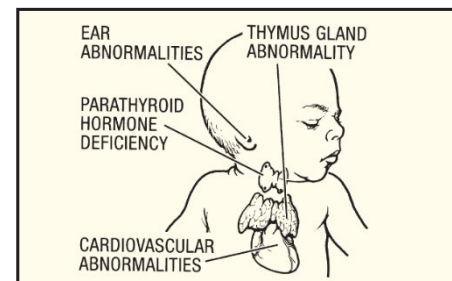
Skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphism; cleft palate.

#### Internal Abnormalities

CNS abnormalities including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit; cardiovascular abnormalities; thymus gland abnormalities; parathyroid hormone deficiencies. In some cases, death has occurred with certain of the abnormalities noted.



Line drawing represents the possible abnormalities of the low-set, deformed, or absent ears; wide-set eyes; depressed bridge of nose; enlarged head; and small chin.



Line drawing represents the possible abnormalities of the brain, heart, and thymus gland that may occur

## Pregnancy After Isotretinoin Treatment

The terminal elimination half-life of isotretinoin varies but is generally within 10 to 20 hours. The elimination half-life of one of the isotretinoin metabolites, 4-oxoisotretinoin, is approximately 25 hours. Since plasma elimination is host dependent, prescribers should warn patients not to get pregnant for 1 month post treatment. Patients who get pregnant during this month should be counseled as to the outcome data. In 1989, Dai et al reported the results of an epidemiologic study of pregnancies that occurred in women who conceived after discontinuing isotretinoin.<sup>2</sup> They studied women from 5 days to more than 60 days between the last dose of isotretinoin and conception. The incidence of birth defects in former isotretinoin patients was not significantly different from the rate in the general population.

Isotretinoin is found in the semen of male patients taking isotretinoin, but the amount delivered to a partner would be about 1 million times lower than an oral dose of 40 mg. While the no-effect limit for isotretinoin-induced embryopathy is unknown, 20 years of post-marketing reports include 4 with isolated defects compatible with features of retinoid-exposed fetuses; however, 2 of these reports were incomplete, and 2 had other possible explanations for the defects observed.

## Other Important Safety Information

Isotretinoin may cause depression, psychosis, and or suicide. Some patients taking isotretinoin have had thoughts about hurting themselves or suicidal thoughts. Instruct the patient to stop isotretinoin and call their prescriber right away if the patient or a family member notices any signs and symptoms of depression or psychosis.

## What is the iPLEDGE<sup>®</sup> REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the Food and Drug Administration (FDA) to help ensure that the benefits of a drug outweigh its risks. When there is a REMS, drug companies, healthcare providers, and pharmacies must take extra steps to make sure the benefits of using the drug are greater than the risks. Because of the serious risk of embryo-fetal toxicity, isotretinoin is available only under a special restricted distribution REMS called “iPLEDGE REMS.”

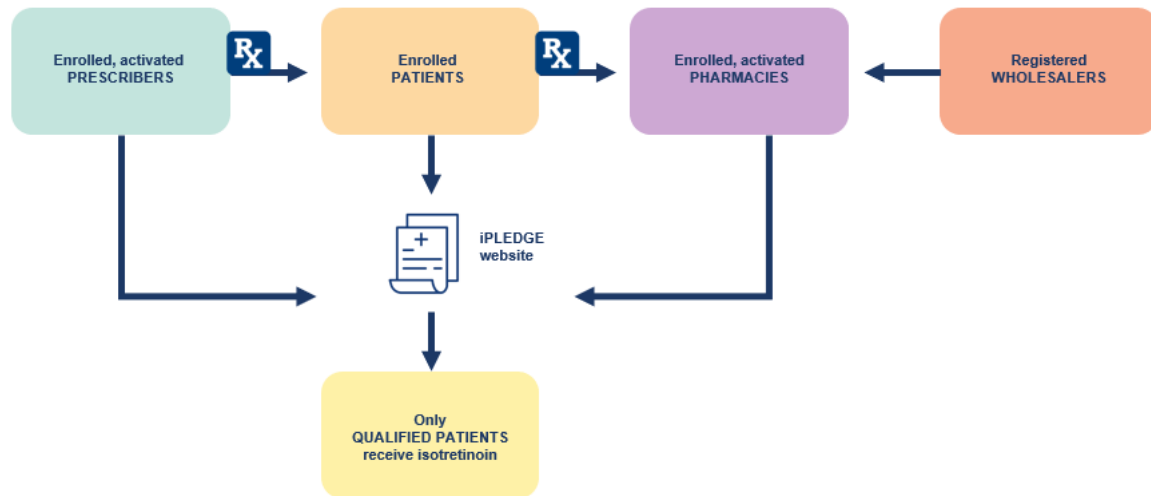
The iPLEDGE REMS is a computer-based risk management system that uses verifiable, traceable links between the prescriber, patient, pharmacy, and wholesaler to control prescribing, using, dispensing, and distribution of isotretinoin. The iPLEDGE REMS is a shared (includes multiple manufacturers) Risk Evaluation and Mitigation Strategy (REMS) with requirements for prescribers, pharmacies, patients, and wholesalers. The iPLEDGE REMS also includes a pregnancy registry for patients who get pregnant.

The goal of the iPLEDGE REMS is to mitigate the risk of embryo-fetal toxicity

- a. Patients' reproductive status is assessed.
- b. Patients who can get pregnant agree to use contraception or abstinence to prevent fetal exposure.
- c. Patients who can get pregnant have a negative confirmatory pregnancy test result before treatment initiation to prevent fetal exposure.
- d. Patients who can get pregnant have a negative pregnancy test result prior to each dispense during treatment to minimize fetal exposure.

Isotretinoin must only be prescribed by prescribers enrolled and activated in the iPLEDGE REMS. Isotretinoin must only be dispensed by pharmacies enrolled and activated in the iPLEDGE REMS and must only be dispensed to patients who are enrolled by their prescriber/doctor and meet all the requirements of the iPLEDGE REMS (see the isotretinoin Prescribing Information).

#### Traceable links of the iPLEDGE REMS



## How do pharmacies enroll in the iPLEDGE REMS?

Each pharmacy in the iPLEDGE® REMS must designate a pharmacist as the Authorized Representative. The Authorized Representative is the point of contact for the pharmacy and the iPLEDGE REMS.

The Authorized Representative performs the following tasks:

- Reviews the **Pharmacist Guide**
- Enrolls the pharmacy with the iPLEDGE REMS by completing and submitting **the Pharmacy Enrollment Form** on the iPLEDGE REMS website.
  - Visit [www.ipledgeprogram.com](http://www.ipledgeprogram.com) and select **PHARMACIES** in the menu across the top of the page.
- Activates the pharmacy enrollment initially and agrees to the REMS requirements.
- Re-activates the pharmacy annually.
  - Pharmacists will not be able to obtain authorization to dispense isotretinoin at a pharmacy that is not activated in the REMS
- Trains, at enrollment and annually thereafter, all relevant staff who participate in the filling and dispensing of isotretinoin prescriptions and keeps a log or record of the staff who have been trained
- Informs all trained pharmacists interacting with the iPLEDGE REMS system that they should create a personal account by calling the Contact Center.

## Activation

Before a pharmacist can fill and dispense prescriptions for isotretinoin, the Authorized Representative must activate the pharmacy's enrollment in the iPLEDGE REMS website. The REMS activation expires annually. The Authorized Representative, representing the pharmacy, must activate annually to continue ordering, filling, and dispensing isotretinoin.

If your pharmacy's activation expires, and you do not intend to reactivate, you must return all unused isotretinoin immediately to the manufacturer or delegate.

The iPLEDGE REMS website will report the expiration date of a pharmacy's enrollment. To retrieve this information on the website, log in and choose the Manage Pharmacies button. In the phone system, log in and select the option to hear "Program Status."

During the pharmacy enrollment and activation process, the Authorized Representative must review and acknowledge the Pharmacy Agreement.

## Authorized Representative Responsibilities

### Training Pharmacy Staff

The Authorized Representative is responsible for the annual training, and the documentation of training, of all relevant staff who participate in the filling and dispensing of isotretinoin prescriptions at an enrolled pharmacy.

The annual training for all relevant staff must include:

- Knowing about isotretinoin embryo-fetal toxicity and the contraception and REMS requirements
- Being able to access the REMS website and obtain authorization to fill and dispense a prescription
- Correctly using the RMA number and, for patients who can get pregnant, the "Do Not Dispense To Patient After" date
- Establish processes and procedures to reverse the authorization to dispense the prescription when isotretinoin is returned to inventory.
- Familiarity with the **Non-Compliance Action Policy** and the sanctions that can occur for pharmacy non-compliance activities

Training begins by providing the **Pharmacist Guide** to all pharmacists. Additional copies can be requested through the REMS website and the iPLEDGE REMS phone system.

### Managing Pharmacies

Pharmacy Authorized Representatives are responsible for managing the pharmacy profile in the iPLEDGE REMS system. To do so, login into the iPLEDGE REMS website and select **Manage Pharmacies**.

Authorized Representatives can complete the following activities on the Manage Pharmacies page:

- Annual pharmacy re-activation
- Editing pharmacy profile data
- Deleting a pharmacy from the iPLEDGE REMS system

Relevant staff who participate in the filling and dispensing of isotretinoin prescriptions can use the Manage Pharmacies page to view pharmacy profile data.

## Changing The Authorized Representative

The pharmacy can change its designated Authorized Representative at any time. To make the change, the new Authorized Representative or the former Authorized Representative must call the iPLEDGE<sup>®</sup> REMS at **1-866-495-0654** and select the pharmacy option, then select 0 to transfer to the Contact Center.

The new Authorized Representative must re-activate the pharmacy in the iPLEDGE REMS (for activation information, **see page 6**). If the pharmacy activation expires and you do not intend to reactivate, you must return all unused isotretinoin immediately to the manufacturer or their delegate.

## Pharmacy Requirements for Dispensing

- Before dispensing, I must:
  - For patients who can get pregnant:
    - Obtain authorization to dispense each prescription by contacting the REMS to verify if the prescriber is certified, the patient is enrolled, the patient counseling is complete, the patient is not pregnant, the patient's contraception choices or commitment to abstinence is confirmed, the patient's monthly comprehension questions are complete, and dispensing is within the designated timeframe.
  - For patients who cannot get pregnant:
    - Obtain authorization to dispense each prescription by contacting the REMS to verify if the prescriber is certified the patient is enrolled.
  - Document the authorization number for each prescription through the processes and procedures established as a requirement of the REMS.
- At all times, I must:
  - Not dispense more than a 30 days' supply.
  - Not dispense refills.
  - For patients who can get pregnant:
    - Not dispense after the date provided by the REMS, reverse the authorization to dispense the prescription, and return isotretinoin to inventory through the processes and procedures established as a requirement of the REMS.
  - For patients who cannot get pregnant:
    - Reverse the authorization to dispense the prescription when isotretinoin is returned to inventory through the processes and procedures established as a requirement of the REMS.

- Return unused product to the manufacturer.
- Not distribute, transfer, loan, or sell isotretinoin.
- Maintain records of staff's completion of training.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by the Isotretinoin Applicants, or a third party acting on behalf of the Isotretinoin Applicants to ensure that all processes and procedures are in place and are being followed.

## Patient Criteria For Authorization To Fill And Dispense

This is the information that must be entered by prescribers, patients, and pharmacists into the iPLEDGE REMS website for all patients and, specifically, for patients who **can get** pregnant. This is the information the system uses to authorize filling a prescription, to provide the RMA number and for patients who can get pregnant, the “Do Not Dispense To Patient After” date.

### All patients

#### Prescriber:

- Enrolls the patient in the iPLEDGE REMS
- Counsels the patient about the iPLEDGE REMS requirements at enrollment

### Patients who can get pregnant (prior to each prescription)

#### Prescriber:

- Confirms that the patient was counseled about the iPLEDGE REMS pregnancy prevention requirements and REMS requirements
- Enters the **2** forms of contraception that the patient is using or the patient's commitment to abstinence
- Enters pregnancy test results to start the 7-day prescription window, counting the date of the specimen collection as DAY 1

#### Patient:

- Correctly answers the comprehension questions
- Enters the **2** forms of contraception the patient is using or the patient's commitment to abstinence

The pregnancy prevention methods reported by both the prescriber and the patient must match. If the patient chooses contraception, the 2 forms of contraception reported by the patient and prescriber must match.

#### Pharmacist:

- To obtain authorization to dispense, enters the patient name and iPLEDGE REMS Patient ID and isotretinoin product/prescription information into the REMS

If the patient is qualified to receive isotretinoin then the REMS will generate a risk management authorization (RMA). The system will automatically provide the pharmacist with the “Do Not Dispense To Patient After” date. The pharmacist must not dispense the prescription after this date. It is recommended that pharmacists document this date on the prescription bag. If the patient does not pick up the prescription by this date, the pharmacist must reverse the authorization to dispense the prescription and return isotretinoin to inventory through the processes



## Patients who cannot get pregnant

### Pharmacist:

- To obtain authorization to dispense:
  - Enters the patient name and iPLEDGE REMS Patient ID
  - Enters the prescriber's NPI number to ensure the Prescriber is activated in the iPLEDGE REMS
  - Enters the isotretinoin product/prescription information











If the patient is qualified to receive isotretinoin then the REMS will generate a risk management authorization (RMA). If the patient does not pick up the prescription, the pharmacist should reverse the authorization to dispense the prescription in the REMS system, and return isotretinoin to inventory.

# Pregnancy Prevention Requirements

iPLEDGE® REMS Approved Forms of Contraception



## Choose 1 Primary + 1 Secondary Birth Control Form

Primary Form of Birth Control (Choose One)*	How to Use it		How Well it Works	Benefits †	Risks †
<b>Hormonal Implant</b>  ‡	Placed under the skin of the arm by a clinician. Works for 3 years. <sup>1</sup>	 MORE EFFECTIVE	>99% <sup>1</sup>	<ul style="list-style-type: none"> <li>Nothing to do or remember</li> <li>Light or no periods</li> <li>May decrease acne</li> <li>No increased risk of clots</li> </ul>	<ul style="list-style-type: none"> <li>Irregular periods</li> <li>Does not prevent the spread of any sexually transmitted infections (STIs) or HIV/AIDS</li> </ul>
<b>Hormonal IUD</b> 	Placed in the uterus by the clinician. Self-check monthly. Works for 3-5 years. <sup>1,2,3</sup>		>99% <sup>1</sup>	<ul style="list-style-type: none"> <li>Light or no periods</li> <li>No increased risk of clots</li> </ul>	<ul style="list-style-type: none"> <li>Irregular periods</li> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>
<b>Non-Hormonal IUD</b> 	Placed in the uterus by the clinician. Self-check monthly. Works for 10 years. <sup>4</sup>		>99% <sup>1</sup>	<ul style="list-style-type: none"> <li>No hormones</li> <li>Periods remain regular</li> <li>Effective immediately</li> <li>No increased risk of clots</li> </ul>	<ul style="list-style-type: none"> <li>May cause heavier periods and cramping</li> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>
<b>Tubal Sterilization</b> 	A surgical procedure to close the tubes between the uterus and the ovaries.		>99% <sup>5</sup>	<ul style="list-style-type: none"> <li>It is a virtually permanent form of birth control</li> <li>Nothing to do or remember</li> </ul>	<ul style="list-style-type: none"> <li>If you want to have a child later, it is very difficult to re-open the tubes</li> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>
<b>Male Vasectomy</b> 	A surgical procedure that closes off the tubes that carry a partner's sperm.		>99% <sup>5</sup>	<ul style="list-style-type: none"> <li>It is a virtually permanent form of birth control</li> <li>Nothing to do or remember</li> </ul>	<ul style="list-style-type: none"> <li>If you want to have a child later, it is very difficult to re-open the tubes</li> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>
<b>Hormonal Shot</b> 	Given every 3 months by a clinician.		>97% <sup>1</sup>	<ul style="list-style-type: none"> <li>Light or no periods</li> <li>No increased risk of clots</li> </ul>	<ul style="list-style-type: none"> <li>Irregular periods</li> <li>May cause weight gain</li> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>
<b>Vaginal Ring</b> 	You place it in the vagina. Replace per prescriber's instructions.		92% <sup>1</sup>	<ul style="list-style-type: none"> <li>Lighter periods</li> <li>May decrease acne</li> </ul>	<ul style="list-style-type: none"> <li>Blood clots</li> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>
<b>Hormonal Patch</b> 	You place it on the skin. Replace weekly.		92% <sup>1</sup>	<ul style="list-style-type: none"> <li>Lighter periods</li> <li>May decrease acne</li> </ul>	<ul style="list-style-type: none"> <li>Blood clots</li> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>
<b>Birth Control Pill (Combination Type)</b> 	Swallow at the same time daily.	92% <sup>1</sup>	<ul style="list-style-type: none"> <li>Lighter periods</li> <li>May decrease acne</li> </ul>	<ul style="list-style-type: none"> <li>Blood clots</li> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>	

**Choose 1 Primary + 1 Secondary Birth Control Form**

Secondary Form of Birth Control (Choose One)	How to Use it	How Well It Works	Benefits	Risks
<b>Male Latex Condoms</b> (with or without spermicide)	Partner must be willing to use each and every time you have sex.	87% <sup>6</sup>	<ul style="list-style-type: none"> <li>Protects from STIs and HIV/AIDS</li> </ul>	
<b>Cervical Cap</b> (must be used with spermicide)	Place in vagina before you have sex.	78% <sup>6</sup>	<ul style="list-style-type: none"> <li>You are in control of its use</li> </ul>	<ul style="list-style-type: none"> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>
<b>Diaphragm</b> (must be used with spermicide)	Place in vagina before you have sex.	83% <sup>6</sup>	<ul style="list-style-type: none"> <li>You are in control of its use</li> </ul>	<ul style="list-style-type: none"> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>
<b>Vaginal Sponge</b>	Place in vagina before you have sex.	83% <sup>6</sup>	<ul style="list-style-type: none"> <li>You are in control of its use</li> </ul>	<ul style="list-style-type: none"> <li>Does not prevent the spread of any STIs or HIV/AIDS</li> </ul>

\*Consult your doctor if you are considering choosing 2 primary forms of birth control rather than a primary and secondary form.

<sup>†</sup>Benefits and Risks are not inclusive. Please review Full Prescribing Information for the products listed.

<sup>‡</sup>All pictograms from FDA website [www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm356451.pdf](http://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm356451.pdf). Accessed January 20, 2016.

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5. Trussell, J. Contraception failure in the United States. *Contraception.* 2011;83:397-404. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3638209/>. Accessed September 9, 2014. 6. Bradley SEK, Polis CB, Micks EA, Steiner MJ. Effectiveness, safety, and comparative side effects. In: Cason P, Cwiak C, Edelman A, et al, eds. *Contraceptive Technology.* 22nd ed. Jones & Bartlett Learning; 2023:130-131

## Abstinence

For this REMS, all patients who **can** get pregnant must fully commit to pregnancy prevention. Isotretinoin is not recommended for any patient who **can** get pregnant who cannot or will not follow the pregnancy prevention requirements of the iPLEDGE® REMS.

Abstinence may be appropriate when it is a lifestyle choice, such as religious practice, and not just a social circumstance, such as not having a current partner. If, after counseling, a sexually active patient chooses abstinence, the patient must understand that the patient has committed to not having any sexual contact (**penis-vaginal**) with a partner that could result in pregnancy for 1 month before starting taking isotretinoin, while on isotretinoin and for 1 month after stopping isotretinoin.

A patient who switches pregnancy prevention methods during treatment from abstinence to 2 forms of iPLEDGE approved contraception is required to wait for 30 days while consistently using 2 forms of birth control before continuing treatment. The patient will be required to have a negative pregnancy test, completed in a medical setting (e.g., prescriber’s office, clinic, laboratory), which starts the 30-day wait period. When the 30-day wait period is over, the patient will need to have a second negative pregnancy test completed in a medical setting (e.g., prescriber’s office, clinic, laboratory), be confirmed by the prescriber in the iPLEDGE REMS system, and then complete the comprehension questions before continuing treatment.

**One of the most common reasons for pregnancy is engaging in sexual contact (penis-vaginal) with a partner that could result in pregnancy when planning to be abstinent.**

## Unacceptable Forms of Contraception Include:

- Progesterone-only “mini-pills”, this includes the over-the-counter birth control option
  - Female condoms
  - Natural family planning (rhythm method or fertility awareness)
  - Breastfeeding
  - Withdrawal
  - Cervical shield\* a silicone disc with a one-way air valve that creates suction to adhere to the cervix \*
- \*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.

Patients currently using these unacceptable forms of contraception must switch to the iPLEDGE REMS approved forms of contraception at least 1 month before starting isotretinoin.

## What Should a Patient Know if Their Contraception Fails or if They Have Unprotected Sex?

### Emergency Contraception

**Emergency birth control is meant only for emergencies. It does NOT take the place of the patient’s usual 2 forms of birth control, and it will not protect against sexually transmitted infections (STIs). Emergency birth control is not to be used instead of regular birth control and it does not work if the patient is already pregnant.**

Emergency birth control is also called “after sex” or “morning after” birth control. It can prevent pregnancy after sex (penis-vaginal) without adequate protection. Emergency birth control prevents release of the egg, joining of the sperm and the egg, or implanting of the egg in the uterus. Emergency birth control is only for a patient who is sure they are not already pregnant.<sup>1</sup>

Emergency Contraceptive Pills (ECPs)—some must be used within 3 days; others must be used within 5 days of having sex (penis-vaginal) without adequate protection. The sooner the patient takes ECPs, the more likely they are to work. It is best if ECPs are started within 12 hours after having sex without adequate protection.<sup>1</sup> Advise the patient that ECPs may cause severe nausea and advise the patient to contact their prescriber for appropriate treatment. ECPs do not take the place of the patient’s usual birth control, nor do they continue to prevent pregnancy during the rest of the menstrual cycle.

1: Emergency Contraception Review: Evidence-based Recommendations for Clinicians: Cleland K, Raymond E, Westley E, Trussel J. Clin Obstet Gynecol. 2014 Dec;57(4):741–750

### When Would a Patient Need Emergency Birth Control?

A patient may need emergency birth control if they have had sex (penis-vaginal) without adequate protection, such as:

- Forgetting to take 2 or more birth control pills and had sex
- Having sex without using a second form of birth control
- Being late for their birth control hormonal shot and had sex
- Their partner’s condom broke or slipped off
- Their diaphragm or cervical cap slipped out of place or ripped during sex

## Where can a patient get emergency birth control?

A patient can get emergency birth control from:

- Private doctors or nurse practitioners
- Planned Parenthood
- Women's health centers
- Many hospital emergency rooms (unless they are owned by organizations opposing birth control)
- Available over the counter at pharmacies

The patient should also realize that emergency contraception should not be used on a regular basis as a replacement for the other contraceptive forms selected.

## What Happens If a Patient Gets Pregnant?

### Counseling a Potentially Pregnant Patient

If a patient expresses concern that they may be pregnant, tell the patient to stop taking isotretinoin immediately and call the prescriber.

## Non-Compliance Action Policy (NCAP)



### Non-Compliance Action Policy (NCAP)

The Non-Compliance Action Policy was implemented to monitor compliance, address deviations, and institute appropriate corrective actions to improve minimization of drug exposure during pregnancy and compliance with elements to assure safe use under the iPLEDGE REMS. The NCAP sets forth the principles by which Non-Compliance by iPLEDGE REMS stakeholders will be evaluated. The NCAP can be found on the iPLEDGE REMS website at [www.ipledgeprogram.com/#Main/Resources](http://www.ipledgeprogram.com/#Main/Resources).



[www.ipledgeprogram.com](http://www.ipledgeprogram.com)  
1-866-495-0654



**IMPORTANT NOTE:** Per the Non-Compliance Action Policy (NCAP), any pharmacy that receives a denial to fill the prescription in the iPLEDGE REMS website, but dispenses the prescription without an RMA will be subject to a 90-day Temporary Deactivation.