

iPledge

iPledge



What Is iPledge?

The iPledge program has defined itself as...

“a computer-based risk management program designed to further the public health goal to eliminate fetal exposure to Isotretinoin through a special restricted distribution program approved by the FDA.”

What Is iPledge?



iPledge

The requirements affecting all patients include...

- Every patient in the US **must** participate.
- All patients (and parents if minor) must sign a written consent for treatment.
- All patients on Isotretinoin must be seen **monthly**.
- Patients cannot be prescribed more than a 30-day supply of Isotretinoin at a time.

FCBP Group

“Females of Child Bearing Potential” (FCBP)

- Females who are *physically capable* of becoming pregnant.
 - 12 year-old girl?
 - 20 year-old college student?
 - 40 year-old Catholic nun?
- *Even patients who have had a tubal ligation are considered FCBP!*

YES!

FCCBP Group

Which women *aren't* considered "Females of Child Bearing Potential"?

- Those who...
 - Have documented ovarian failure (inability to ovulate).
 - Have had bilateral oophorectomy (both ovaries removed) and/or hysterectomy.
 - Are postmenopausal.

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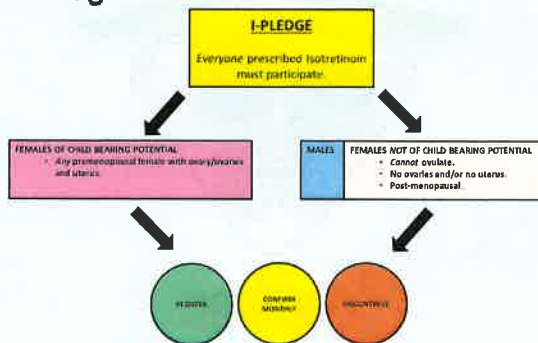
Males & FCCBP

Males & "Females NOT of Child Bearing Potential" (FCCBP)

- These are patients *incapable* of becoming pregnant.
 - However, IF these patients were to "share" medicine with someone else or donate blood while on (or within 30 days of discontinuing) Isotretinoin, the medication could *potentially* find its way indirectly to a pregnant female.

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iPledge



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Registering Males & FCCBP

Steps to registering these patients include...

- Providing the patient (and parents if minor) with iPledge information to review.
 - The thinner "Introductory Brochure" should only be given to patients *thinking about* treatment.
 - The thicker "Program Guide" should be given to patients who are *ready* to be registered in iPledge.
 - **Consent form must be signed!**
 - There are a wide range of *potential* side effects.
 - Let your SP know if a patient wanting Isotretinoin has *either* a personal or a strong family history of depression, suicidal ideation, Crohn's Disease, or ulcerative colitis!

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Registering Males & FNCBP

Steps to registering these patients include...

- Monitoring Labs?
 - Monitoring CBC, Lipids, and Hepatic Function is *not* a requirement of iPledge!
 - “When” and “how often” monitoring labs are checked is *entirely up to the preferences of your supervising physician.*

Registering Males & FNCBP

- Obtain signed consent.
 - Retain original (top) copy for patient’s chart.
- ***Once consent is signed, patients in this group can be registered!***
- iPledge website - www.ipledgeprogram.com
 - Username and password required.
 - If entering patient information into iPledge is part of your routine job duties, your supervising physician really should register you as a designee.

Registering Males & FNCBP

To register these patients, in addition to the signed consent and patient demographics, you will need...

- I-Pledge number.
 - Found within iPledge booklet.
 - Remind patients of the importance of bringing a copy of ID card with them to the pharmacy!



Registering Males & FNCBP

To register these patients, in addition to the signed consent and patient demographics, you will need...

- Last 4 digits of patient's Social Security number.
 - Without the last 4 digits of SS number, **you may need to get on the phone** with iPledge in order to complete registration.
- Patient's e-mail address.
 - If iPledge sends any needed information to the patient through the postal service and they don't receive it, **guess who will be making a call to iPledge?**

Registering Males & FNCBP

**iPledge Demonstration
Video Here**

Confirming Males & FNCBP

- Males and FNCBP may be prescribed Isotretinoin *immediately* after registration.
- "Confirmation" within iPledge is mandatory *every time* a prescription is given.

Confirming Males & FNCBP

**iPledge Demonstration
Video Here**

Confirming Males & FNCBP

- After confirmation, patients in this group have *up to 30 days* to fill their prescription.
 - **Best to avoid emphasizing this to patients!**
 - Patients should *always* be instructed to fill their prescriptions right away.

Discontinuing Males & FNCBP

**iPledge Demonstration
Video Here**

Registering FCBP

To register these patients, you initially perform the same steps as the last group, including...

- Provide patient (and parents if minor) with iPledge program guide to review.
 - There are **two** consent forms for this group.
 - [General informed consent](#) that all patients must sign, plus...
 - Informed consent about [birth defects](#).
 - Monitoring Labs?
 - Any testing of CBC, Hepatic Function, or Lipids is per your office protocol and technically *is not* a requirement of iPledge.



Registering FCBP

iPledge requires that all patients in this group must commit to abstinence OR the use of 2 forms of birth control for at least 30 days prior, during, and 30 days after treatment.

Registering FCBP

iPledge Contraceptive Requirements

- At least one method must be a **primary** form of birth control as defined in "[Item 5](#)" of the birth defect consent form.
- The second method can be any of the "other" methods listed in "[Item 5](#)".

Registering FCBP

iPledge requires that all patients in this group must commit to abstinence OR the use of 2 forms of birth control for at least 30 days prior, during, and 30 days after treatment.

Registering FCBP

Referral For Contraceptive Counseling

- [Referral form](#) is found within the iPledge booklet.
 - Technically speaking, referral to another provider is **not** mandatory.
 - All that iPledge requires is that these patients have been counseled and, if sexually active, use two forms of birth control as previously described.
 - If patient *is* referred for counseling, the iPledge program offers to reimburse the other provider for this counseling.
 - [Reimbursement form](#) found in educational kit.

Registering FCBP

Abstinent Patients

- If a patient is **truly** abstinent, she may choose that as her primary birth control method.
 - If abstinence is chosen as **primary** method, there is no need for a **secondary** method.

Registering FCBP

To register FCBP patients into iPledge, you will need...

- Patient's name, address, etc.
- Signed copy of **both** consents.
- Patient's iPledge number.
- Last 4 digits of patient's Social Security number.
- Patient's e-mail address.
- Negative hCG (pregnancy) test within last 30 days.
 - May be performed in the office or as part of baseline labs.

Registering FCBP

The "30-Day" Waiting Period

- All patients in this group **must** wait 30 days before they can be prescribed Isotretinoin!
 - Done so that a second pregnancy test can be performed immediately prior to patient receiving initial Rx, thereby adding an "extra" element of certainty that the patient is not pregnant.
 - The "30-Day" countdown doesn't begin until the patient is initially registered.

Registering FCBP

**iPledge Demonstration
Video Here**

Confirming FCBP

These patients must be confirmed whenever they are prescribed Isotretinoin. Steps include:

- Reminding patient to avoid pregnancy.
- Pregnancy test must be repeated **monthly**.
 - The date of the pregnancy test begins a "7 day window" within which the patient must fill the prescription.
 - A repeat pregnancy test must be performed if the patient fails to fill her prescription within the "7 day window".
 - iPledge allows patients to be confirmed with urine hCG!
 - If not already doing so, consider performing urine hCG (if able) on the day of follow-up visit.

Confirming FCBP

**iPledge Demonstration
Video Here**

Confirming FCBP

After FCBP patients have been confirmed in iPledge, they must...

- Log on to www.ipledgeprogram.com with the username/password that iPledge has provided them.
 - Patient must confirm that they understand the need to avoid pregnancy.
 - Patient must also enter their forms of contraception.
 - **IMPORTANT**
 - PATIENTS MUST ENTER THE SAME CONTRACEPTIVE METHODS - IN THE SAME ORDER - EACH TIME!

Also important for us to know that patients can't log on and do their part until after we've confirmed them on our end!

Discontinuing FCBP

When patients in this group finish treatment...

- Log on to iPledge and discontinue as we'll see in the next slide.
- iPledge will ask for a negative pregnancy test at:
 - The conclusion of treatment, **AND**
 - 30 days after the last dose has been taken!

Discontinuing FCBP

iPledge Demonstration Video Here

iPledge



**iPledge
Males/FNCBP
"Cheat Sheet"**



**iPledge
FCBP
"Cheat Sheet"**

Conclusion

**iPledge Phone Support
Available Mon-Sat 9 AM-12 Midnight
1-866-495-0654**

Choose 1 Primary + 1 Secondary Birth Control Method

Primary Method of Birth Control (Choose One)*	How to Use it	MORE EFFECTIVE	How Well it Works	Benefits ¹	Risks ¹
Hormonal Implant 	Placed under skin of arm by a clinician. Works for 3 years. ¹		>99% ¹	<ul style="list-style-type: none"> • Nothing to do or remember • Light or no periods • May decrease acne • No increased risk of clots 	• Irregular Periods
Hormonal IUD 	Placed in uterus by clinician. Self-check monthly. Works for 5 years. ¹		>99% ¹	<ul style="list-style-type: none"> • Light or no periods • No increased risk of clots 	• Irregular Periods
Non-Hormonal IUD 	Placed in uterus by a clinician. Self-check monthly. Works for 10 years. ³		>99% ¹	<ul style="list-style-type: none"> • No hormones • Periods remain regular • Effective immediately • No increased risk of clots 	• May cause heavier periods and cramping
Tubal Sterilization 	Surgical procedure to close the tubes between the uterus and the ovaries.		>99% ²	<ul style="list-style-type: none"> • It is a virtually permanent method of birth control • Nothing to do or remember 	• If you want to have child later, it is very difficult to re-open the tubes
Male Vasectomy 	Surgical procedure that closes off the tubes that carry a partner's sperm.		>99% ²	<ul style="list-style-type: none"> • It is a virtually permanent method of birth control • Nothing to do or remember 	• If you want to have child later, it is very difficult to re-open the tubes
Hormonal Shot 	Given every 3 months by a clinician.		>97% ¹	<ul style="list-style-type: none"> • Light or no periods • No increased risk of clots 	<ul style="list-style-type: none"> • Irregular Periods • May cause weight gain
Vaginal Ring 	You place in vagina. Replace monthly.		92% ¹	<ul style="list-style-type: none"> • Lighter periods • May decrease acne 	• Blood clots
Hormonal Patch 	You place on skin. Replace weekly.		92% ¹	<ul style="list-style-type: none"> • Lighter periods • May decrease acne 	• Blood clots
Birth Control Pill (Combination Type) 	Swallow at the same time daily.	92% ¹	<ul style="list-style-type: none"> • Lighter periods • May decrease acne 	• Blood clots	

Secondary Method of Birth Control (Choose One)	How to Use it	Benefits	Risks
Condoms (with or without spermicide)	Partner must be willing to use each and every time you have sex.	<ul style="list-style-type: none"> • Protects from STIs (Sexually Transmitted Infections) and HIV/AIDS 	• Allergic Reactions
Cervical Cap, Diaphragm (must be used with spermicide). Vaginal Sponge	Place in vagina before you have sex.	<ul style="list-style-type: none"> • You are in control of its use 	• Allergic Reactions

One of the most common reasons that women get pregnant is that they engage in sexual activity when they planned to be abstinent. Abstinance means that you commit to not having sex or sexual contact with any male 24 hours a day, 7 days a week for 1 month before, during, and for 1 month after your isotretinoin treatment.

*Consult your doctor if you are considering choosing 2 primary methods of birth control rather than a primary and secondary method.
¹Benefits and Risks are not inclusive. Please review Full Prescribing Information for the products listed.
²All pictograms from FDA website www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm356451.pdf. Accessed January 20, 2016.
³References 1. Werner CA, Papp MJ, Ferris LK, Schwartz EB. Promoting safe use of isotretinoin by increasing contraceptive knowledge. *JAMA Dermatol.* 2015;151(4):389-393. 2. 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. 3. ParaGard® Prescribing Information, Teva Women's Health, Inc., June 2013.