iPLEDGE® Program Birth Control Information Sheet



Choose | Primary + 1 Secondary Birth Control Method

Primary Method of Birth Control (Choose One)*		How to Use it		How Well it Works	Benefits'	Risks!
Hormonal Implant	byac	d under skin of arm linician. s for 3 years, !		>99%1	 Nothing to do or remember Light or no periods May decrease acne No increased risk of clots 	• Irregular Periods
Hormonal IUD	Self-c	Placed in uterus by clinician. Self-check monthly. Works for 5 years.		>99%1	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		MORE EFFECTIVE	>99%1	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	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	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	Light or no periods No increased risk of clots	Irregular Periods May cause weight gain
Vaginal Ring	You place in vagina. Replace monthly.			92%¹	Lighter periods May decrease acne	Blood clots
Hormonal Patch	You place on skin. Replace weekly.			92%1	Lighter periods May decrease acne	Blood clots
Birth Control Pill (Combination Type)	Swallow at the same time daily.			92%1	Lighter periods May decrease acne	Blood clots
Secondary Method of Birth Control (Choose One) How to			o Use it		Benefits	Risks
Condoms (with or without spermicide)		Partner must be willing to use each and every time you have sex.			Protects from STIs (Sexually Transmitted Infections) and HIV/AIDS	Allergic Reactions
/ 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		Place in vagina before have sex.			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 Abstinence 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.

Benefits and Risks are not inclusive. Please review Full Prescribing Information for the products listed.

*All pictograms from FDA website www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm356451.pdf. Accessed January 20, 2016.

References 1. Werner CA, Papic MJ, Ferris LK, Schwartz EB, Promoting safe use of isotretinoin by increasing contraceptive knowledge. [AMA 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..uhi.gov/pmc/articles/PMC3638209/. Accessed September 9, 2014. 3. ParaGard* Prescribing Information, Teva Women's Health, Inc., June 2013.

iPLEDGE® Program Checklist



BEFORE TREATMENT

PLANNING

- ☐ Talk with your doctor about isotretinoin and the iPLEDGE Program
- ☐ **Sign** the Patient Information/Informed Consent (for all patients) form
- ☐ **Sign** the Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form
- ☐ **Have** your first urine or blood pregnancy test, which can be performed at the doctor's office
- □ Registration—ensure your doctor registers you in the iPLEDGE Program. You must be registered for at least 30 days prior to your first prescription.
- ☐ **Get** your patient ID card containing your patient ID number from your doctor. Keep your patient ID number in a safe place.
- ☐ **Receive** your password in the mail

BIRTH CONTROL

- ☐ **Read** the enclosed Birth Control Information Sheet and for additional information on birth control options read the enclosed Birth Control Workbook
- ☐ Talk with your dermatologist, gynecologist, family doctor, or a birth control expert about effective birth control options
- ☐ Choose 2 effective methods of birth control
- ☐ Start using the 2 methods of birth control together for at least 1 month before you start isotretinoin

YOUR FIRST PRESCRIPTION

- ☐ **Have** a second pregnancy test conducted at an approved lab within the first 5 days of your menstrual period (at least 30 days after registration)
- ☐ Answer questions about the iPLEDGE Program and confirm your 2 methods of birth control
 - Note: you can answer your comprehension questions only after your doctor has entered your pregnancy test result in the iPLEDGE Program system
- ☐ **Obtain** your prescription for up to a maximum of a 30-day supply
 - Note: Isotretinoin comes in blister packs of 10 capsules. The pharmacist cannot break a blister pack and provide fewer than 10 capsules
- ☐ **Obtain** your prescription within the 7-day prescription window, counting the date of the pregnancy test as DAY 1
 - If you are not able to obtain your first prescription within the 7-day prescription window, you will be required to wait a minimum of 19 days before you can start this process again
- ☐ Use 2 effective methods of birth control together all the time
- ☐ **Keep** your appointments every month to get a prescription
- ☐ See your doctor for a monthly pregnancy test
- ☐ **Answer** different questions each month about the iPLEDGE Program

DURING TREATMENT

- ☐ Use 2 effective methods of birth control together all the time
- ☐ See your doctor for a monthly pregnancy test
- ☐ **Keep** your appointments every month to get a prescription
- ☐ Confirm your 2 methods of birth control by entering them into the iPLEDGE Program System
- ☐ **Answer** different questions each month about the iPLEDGE Program
 - Note: you can answer your comprehension questions only after your doctor has entered your pregnancy test result in the iPLEDGE Program system
- ☐ Obtain your prescription for up to a maximum of a 30-day supply
- ☐ **Obtain** your prescription within the 7-day prescription window counting the day of the pregnancy test as DAY 1
 - If you do not obtain your prescription within the 7-day prescription window, you will need to go back to your doctor to start this process again
- ☐ Do not donate blood

AFTER TREATMENT

RIGHT AFTER YOUR LAST DOSE

- ☐ Get a pregnancy test after your last dose
- ☐ Confirm that your doctor has entered the results of this pregnancy test into the iPLEDGE Program System
- ☐ Continue using your 2 methods of birth control for 1 month
- ☐ Do not share any leftover isotretinoin with anyone
- Do not donate blood for 1 month after your last dose

ONE MONTH AFTER YOUR LAST DOSE

- ☐ Have a final pregnancy test at 1 month after your last dose
- ☐ Confirm that your doctor has entered the results of this pregnancy test into the iPLEDGE Program System

Web site: www.ipledgeprogram.com Phone system: 1-866-495-0654