



## Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant)

To be completed by the patient (and her parent or guardian\* if patient is under age 18) and signed by her doctor.

Read each item below and initial in the space provided to show that you understand each item and agree to follow your doctor's instructions. **Do not sign this consent and do not take isotretinoin if there is anything that you do not understand.**

\*A parent or guardian of a minor patient (under age 18) must also read and initial each item before signing the consent.

(Patient's Name) \_\_\_\_\_

1. I understand that there is a very high chance that my unborn baby could have severe birth defects if I am pregnant or become pregnant while taking isotretinoin. This can happen with any amount and even if taken for short periods of time. This is why I must not be pregnant while taking isotretinoin.  
Initial: \_\_\_\_\_

2. I understand that I must not get pregnant 1 month before, during the entire time of my treatment, and for 1 month after the end of my treatment with isotretinoin.  
Initial: \_\_\_\_\_

3. I understand that I must avoid sexual intercourse completely, or I must use 2 separate, effective forms of birth control (contraception) **at the same time**. The only exceptions are if I have had surgery to remove the uterus (a hysterectomy) or both of my ovaries (bilateral oophorectomy), or my doctor has medically confirmed that I am post-menopausal.  
Initial: \_\_\_\_\_

4. I understand that hormonal birth control products are among the most effective forms of birth control. Combination birth control pills and other hormonal products include skin patches, shots, under-the-skin implants, vaginal rings, and intrauterine devices (IUDs). Any form of birth control can fail. That is why I must use 2 different birth control methods at the same time, starting 1 month before, during, and for 1 month after stopping therapy every time I have sexual intercourse, even if 1 of the methods I choose is hormonal birth control.  
Initial: \_\_\_\_\_

5. I understand that the following are effective forms of birth control:

<b>Primary forms</b> <ul style="list-style-type: none"> <li>• tubal sterilization (tying your tubes)</li> <li>• partner's vasectomy</li> <li>• intrauterine device</li> <li>• hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring)</li> </ul>	<b>Secondary forms</b> <b>Barrier forms</b> <ul style="list-style-type: none"> <li>• male latex condom with or without spermicide</li> <li>• diaphragm with spermicide</li> <li>• cervical cap with spermicide</li> </ul> <b>Others:</b> <ul style="list-style-type: none"> <li>• vaginal sponge (contains spermicide)</li> </ul>
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A diaphragm and cervical cap must each be used with spermicide, a special cream that kills sperm

I understand that at least 1 of my 2 forms of birth control must be a primary method.  
Initial: \_\_\_\_\_

6. I will talk with my doctor about any medicines including herbal products I plan to take during my isotretinoin treatment because hormonal birth control methods may not work if I am taking certain medicines or herbal products.  
Initial: \_\_\_\_\_

7. I may receive a free birth control counseling session from a doctor or other family planning expert. My isotretinoin doctor can give me an isotretinoin Patient Referral Form for this free consultation.  
Initial: \_\_\_\_\_

**My doctor has answered all my questions about isotretinoin and I understand that it is my responsibility not to get pregnant 1 month before, during isotretinoin treatment, or for 1 month after I stop taking isotretinoin.**

Initial: \_\_\_\_\_

I now authorize my doctor \_\_\_\_\_ to begin my treatment with isotretinoin.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Parent/Guardian Signature (if under age 18): \_\_\_\_\_ Date: \_\_\_\_\_

Please print: Patient Name and Address \_\_\_\_\_ Telephone \_\_\_\_\_

I have fully explained to the patient, \_\_\_\_\_, the nature and purpose of the treatment described above and the risks to females of reproductive potential. I have asked the patient if she has any questions regarding her treatment with isotretinoin and have answered those questions to the best of my ability.

Doctor Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**PLACE THE ORIGINAL SIGNED DOCUMENTS IN THE PATIENT'S MEDICAL RECORD. PLEASE PROVIDE A COPY TO THE PATIENT.**

8. I must begin using the birth control methods I have chosen as described above at least 1 month before I start taking isotretinoin.  
Initial: \_\_\_\_\_

9. I cannot get my first prescription for isotretinoin unless my doctor has told me that I have 2 negative pregnancy test results. The first pregnancy test should be done when my doctor decides to prescribe isotretinoin. The second pregnancy test must be done in a lab during the first 5 days of my menstrual period right before starting isotretinoin therapy treatment, or as instructed by my doctor. I will then have 1 pregnancy test; in a lab:

- every month during treatment
- at the end of treatment
- and 1 month after stopping treatment

I must not start taking isotretinoin until I am sure that I am not pregnant, have negative results from 2 pregnancy tests, and the second test has been done in a lab.  
Initial: \_\_\_\_\_

10. I have read and understand the materials my doctor has provided to me, including *The iPLEDGE Program Guide for Isotretinoin for Female Patients Who Can Get Pregnant*, *The iPLEDGE Birth Control Workbook* and *The iPLEDGE Program Patient Introductory Brochure*.

My doctor provided me and asked me to watch a video about birth control and a video about birth defects and isotretinoin.

I was told about a private counseling line that I may call for more information about birth control. I have received information on emergency birth control.

Initial: \_\_\_\_\_

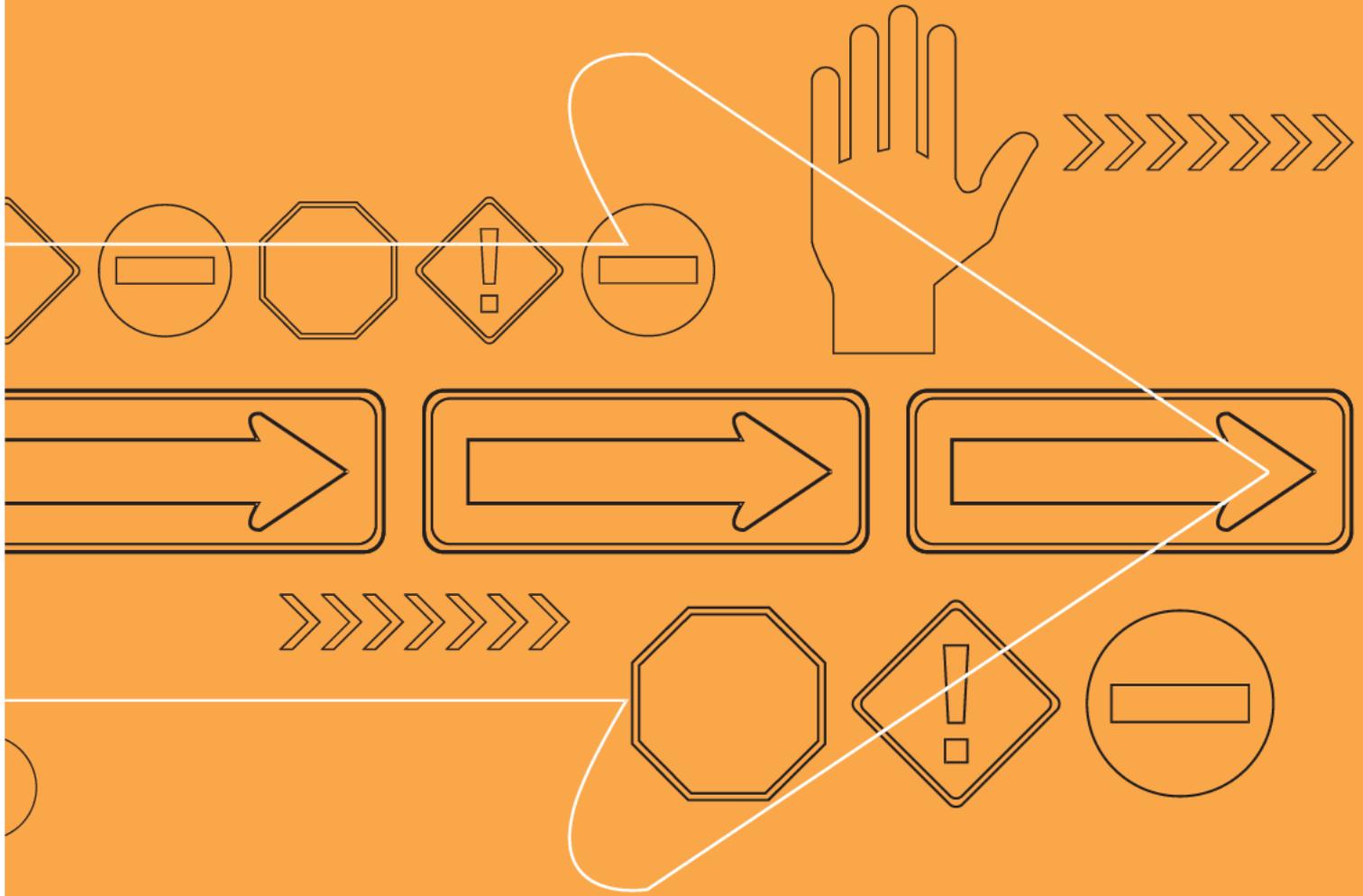
11. I must stop taking isotretinoin right away and call my doctor if I get pregnant, miss my expected menstrual period, stop using birth control, or have sexual intercourse without using my 2 birth control methods at any time.  
Initial: \_\_\_\_\_

12. My doctor provided me information about the purpose and importance of providing information to the iPLEDGE Program should I become pregnant while taking isotretinoin or within one month of the last dose. I understand that if I become pregnant, information about my pregnancy, my health, and my baby's health may be shared with the makers of isotretinoin, authorized parties who maintain the iPLEDGE Program for the makers of isotretinoin, and government health regulatory authorities.  
Initial: \_\_\_\_\_

13. I understand that being qualified to receive isotretinoin in the iPLEDGE Program means that I:

- have had 2 negative urine or blood pregnancy tests before receiving the first isotretinoin prescription. The second test must be done in a lab. I must have a negative result from a urine or blood pregnancy test done in a lab repeated each month before I receive another isotretinoin prescription.
- have chosen and agreed to use 2 forms of effective birth control at the same time. At least 1 method must be a primary form of birth control, **unless I have chosen never to have sexual contact with a male (abstinence)**, or I have undergone a hysterectomy. I must use 2 forms of birth control for at least 1 month before I start isotretinoin therapy, during therapy, and for 1 month after stopping therapy. I must receive counseling, repeated on a monthly basis, about birth control and behaviors associated with an increased risk of pregnancy.
- have signed a Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) that contains warnings about the chance of possible birth defects if I am pregnant or become pregnant and my unborn baby is exposed to isotretinoin.
- have interacted with the iPLEDGE Program before starting isotretinoin and on a monthly basis to answer questions on the program requirements and to enter my two chosen forms of birth control.

Initial: \_\_\_\_\_



> A flowchart to assist you with the iPLEDGE Program requirements

# REGISTERED PATIENTS



Females of reproductive potential (FRP)

Male patients/Females of non-reproductive potential (FNRP)

## BEFORE TREATMENT

- Sign a Patient Information/Informed Consent (for all patients) form for treatment
- Sign a second Patient Information/Informed Consent About Birth Defects (for female patients who can get pregnant) form
- Get a screening urine/blood pregnancy test
- Receive patient ID card
- Choose 2 effective forms of birth control
- Start using the 2 forms of birth control simultaneously for at least 1 month
- Get a second pregnancy test within the first 5 days of your menstrual period (patient with irregular cycle please check with your prescriber) in an approved lab
- Access\* the iPLEDGE Program system to answer questions and to enter the 2 chosen forms of birth control. You can only answer your questions after your doctor has entered your test results into the iPLEDGE Program System
- Get a prescription for a maximum 30-day supply

- Sign a Patient Information/Informed Consent (for all patients) form for treatment
- Receive patient ID card
- Get a prescription for a maximum 30-day supply

## EACH MONTH DURING THERAPY

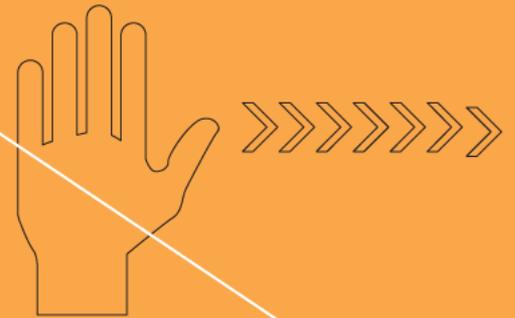
- Use the 2 forms of birth control Simultaneously
- See your doctor for a monthly pregnancy test in an approved lab
- Access\* the iPLEDGE Program system to answer questions and confirm the 2 forms of birth control
- Get a prescription for a maximum 30-day supply
- Do not donate blood

- See your doctor to get a prescription
- Get a prescription for a maximum 30-day supply
- Do not donate blood

## AFTER TREATMENT

- Get a pregnancy test in an approved lab the last dose
- Continue to use the 2 forms of birth control simultaneously for 1 month after the last dose
- Do not donate blood for 1 month after the last dose
- Get a final pregnancy test 1 month after the last dose

- Do not donate blood for 1 month after your last dose



[www.ipledgeprogram.com](http://www.ipledgeprogram.com)

1-866-495-0654

#### WARNING

For your health and safety, please read this booklet carefully. Also, be sure you understand what your doctor has told you about isotretinoin before starting treatment. Do not take isotretinoin if you are pregnant, plan to become pregnant, or become pregnant during isotretinoin treatment. Isotretinoin causes severe birth defects (deformed babies), loss of a baby before birth (miscarriage), death of a baby and early (premature) births. There is no accurate means of determining whether an exposed fetus has been affected.

#### IMPORTANT NOTICE

Use only isotretinoin products approved by the US Food and Drug Administration.

Obtain your isotretinoin prescriptions *only* from pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE Program.



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

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