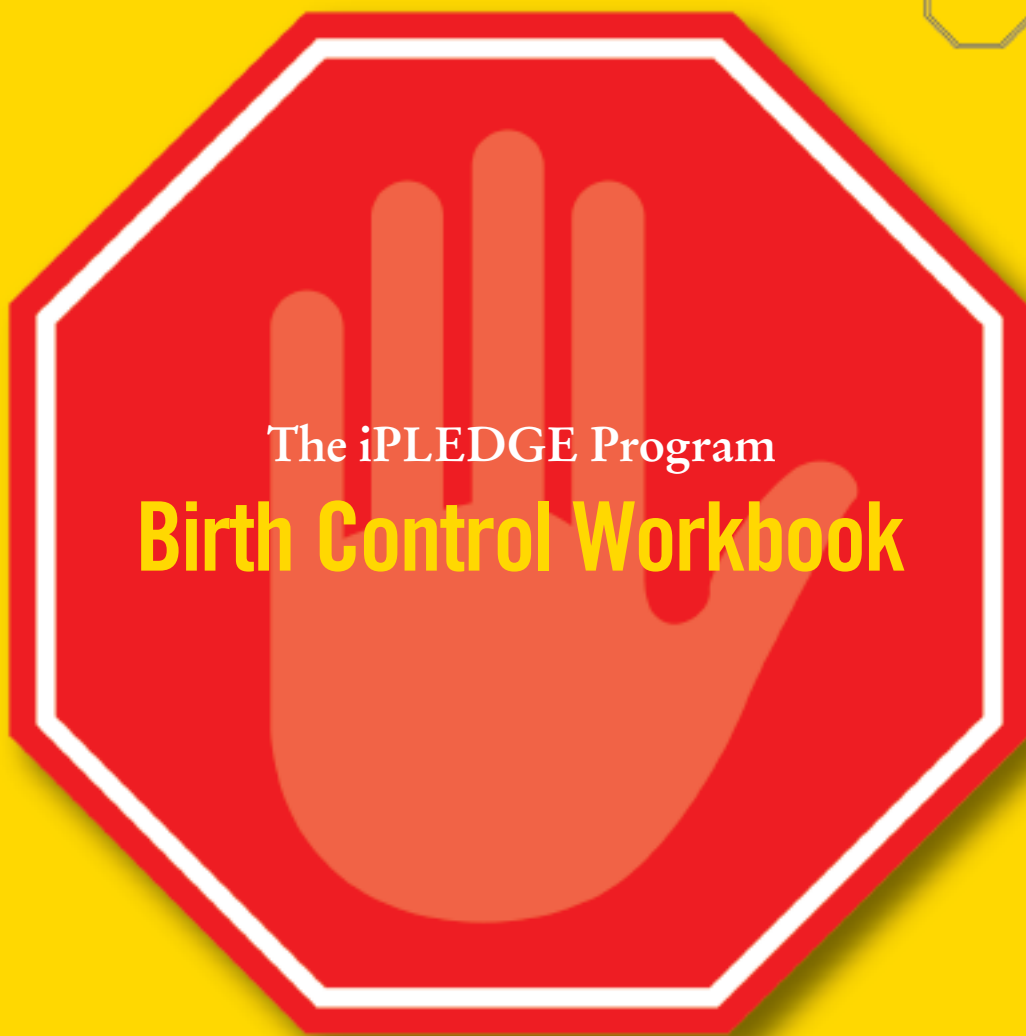
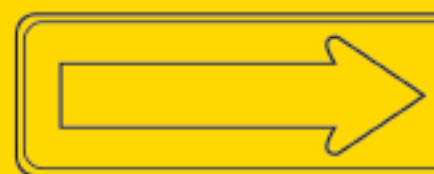




The iPLEDGE Program
Birth Control Workbook



The guide to help
you decide which
forms of birth control
are best for you
during treatment
with isotretinoin

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.

IMPORTANT NOTICE

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

Fill your isotretinoin prescriptions *only* at pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE program.



iPLEDGETM
Committed to Pregnancy Prevention

The iPLEDGE Program Birth Control Workbook

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PREVENTING PREGNANCIES

Not all forms of birth control are effective while you are taking isotretinoin. Choosing birth control is a very personal decision. It helps to get all the information you need and then talk with your doctor to help you decide what to do.

> **Read This Birth Control Workbook**

To find out what birth control is effective for the iPLEDGE program, read this *iPLEDGE Program Birth Control Workbook*. Read it before you make any decisions about birth control. Read it even if you are already using birth control. Read it even if you think you will not have sex with a male for your whole isotretinoin treatment.

After you have read through the booklet, talk it over with someone you trust. Think about what kinds of birth control you would really use. Then talk with your doctor or a birth control expert.

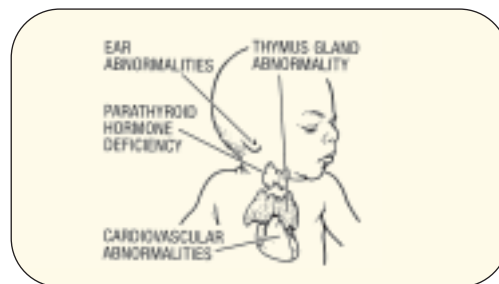
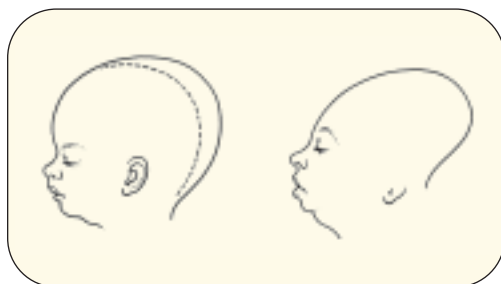
Share this workbook with your partner. Talk with your partner about birth defects and isotretinoin. Explain what you both need to do to prevent pregnancy. Tell him you need to prevent pregnancy for at least 1 month before you start isotretinoin, during your treatment, and for 1 month after your last dose. This can be several months.

Write down a list of questions for your dermatologist, gynecologist, or family doctor. No question is too silly. Make sure you know how to use the birth control forms you choose.



WHY SHOULD I USE THIS WORKBOOK?

You are getting ready to start isotretinoin (eye-soh-tret-in-OH-in). It treats severe acne, but it can also cause birth defects. You must not get pregnant right before starting isotretinoin, while taking it, and for 1 month after your last dose. **There is a very high chance that your baby could be deformed, born too early, or die.** This can happen even if you take isotretinoin for only a short time.



The pictures show some of the birth defects your baby can have. Your baby's head could be deformed; the ears could be an odd shape or even missing. The eyes could be too far apart, the bridge of the nose too low, or the chin smaller than normal. The baby could have mental retardation or severe problems in the glands, heart, and brain.

You do not want to be pregnant or get pregnant right before starting isotretinoin, while taking it, and for 1 month after your last dose.

To keep from getting pregnant, you need to use 2 effective forms of birth control together correctly all the time:

- For at least 1 month before you start isotretinoin
- While you take it—treatment usually lasts 4 to 5 months
- For 1 month after your last dose—you still need protection against pregnancy

This workbook is for ALL female patients who can possibly get pregnant. This means that:

- You are physically able to get pregnant
- You have a uterus and ovaries
- You have menstrual periods

Even if you are not having sex, you still need to follow the requirements of the iPLEDGE program.

> Female Patients Who Cannot Get Pregnant

Female patients who cannot get pregnant are not required to be on birth control. This applies to you if:

- You have entered menopause, and your doctor has confirmed this.
- You have had your ovaries or uterus taken out by surgery, and your doctor has confirmed this.

If you have any questions about being able to get pregnant, talk with your doctor.



HOW SHOULD I USE THIS WORKBOOK?

Use this workbook as a guide to help you decide which 2 effective birth control forms are best for you during your treatment. You will want to pick a birth control form that works for you and gives you the best protection against pregnancy (primary form). Since all forms of birth control can fail, you must also pick a second form (another primary form or a secondary form) that you use every time you have sex.

This workbook also provides information about abstinence, emergency birth control, and issues around conception and pregnancy.



THE iPLEDGE PROGRAM AND BIRTH CONTROL

Referral for birth control counseling

Before beginning treatment, you or the doctor may choose a referral to a birth control expert. The makers of isotretinoin will pay for 1 visit for birth control counseling. The patient educational kit contains *The iPLEDGE Program Contraception Referral Form And Contraception Counseling Guide*. The referral form is in the booklet; the guide outlines the birth control requirements and the effective forms of birth control of the iPLEDGE program for the birth control expert. The referral form should be taken with you to the birth control counselor.

> Why Do I Have To Use 2 Forms Of Birth Control Together?

- Any single birth control form can fail.
- Using 2 forms of birth control together all the time drastically reduces the chance that you will get pregnant.
- Most female patients who got pregnant during isotretinoin treatment were using only 1 form of birth control!

> Can I Use Any 2 Forms Of Birth Control?

No, you must choose from the iPLEDGE program list of effective birth control forms.

The 2 types of birth control you use for the iPLEDGE program are called **primary forms** and **secondary forms**.

- **Primary forms** do not fail very often. Be sure to choose a primary form that gives you the lowest chance of failure. This depends on such things as how well you remember to take medicine every day, whether you have had children or your partner has had a vasectomy, or you have medical problems.
- **Secondary forms** include **barrier forms** and **other forms** of birth control. The most important thing about a secondary form is using it every time you have sex.
 - **Barrier forms** keep sperm from entering the uterus. You use a barrier form with spermicide (a cream that kills sperm).
 - **Other forms** (vaginal sponge) contain spermicide.

> Preventing Pregnancy By Abstinence (Not Having Sex)

Abstinence means that you *will not have sex* or sexual contact with any male 24 hours a day, 7 days a week. This can be hard to do, especially if you are used to having sex.

It is easier not to have sex when it is a lifestyle choice, such as religious practice. One of the most common causes of unplanned pregnancy is not being able to avoid sex (failing to maintain abstinence).

Abstinence is not a recommended way to prevent pregnancy for the iPLEDGE program.

You should really think about using birth control while you are taking isotretinoin, even if you have never had sex—even if you are absolutely 100% certain you will not have any sexual contact with any male before, during, and for 1 month after taking isotretinoin. Isotretinoin is not recommended if you do not follow the birth control requirements of the iPLEDGE program.

> Concerns About Birth Control Pills

Many female patients use birth control pills. But birth control pills can fail, and you can get pregnant. They fail because you forget to take them.

- If you take them every day, they are very effective birth control.
- If you miss pills and do not take them every day, your chance of getting pregnant is much higher with birth control pills than with other primary birth control forms, such as hormonal shots, an intrauterine device (IUD), or the hormonal skin patch.

If you are taking birth control pills, do you remember to take them every day? If not you need to consider another primary form of birth control as you read this workbook.

> The iPLEDGE Program Effective Birth Control Forms

Effective forms of contraception include both primary and secondary forms of contraception:

Primary forms	Secondary forms
• Tying my tubes (tubal sterilization) • Partner's vasectomy • Intrauterine device • Hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring)	<i>Barrier forms (always used with spermicide):</i> • Male latex condom • Diaphragm • Cervical cap <i>Others:</i> • Vaginal sponge (contains spermicide)

You cannot use 2 hormonal forms together. Progesterone-only "mini-pills" are not effective for the iPLEDGE program.

Female condoms are not an effective secondary form for the iPLEDGE program.

➤ Birth Control Forms That Are NOT Acceptable

You cannot use the following forms of birth control while you are taking isotretinoin. They do not give enough protection even when used with a second form of birth control.

- Birth control pills without estrogen (progesterone-only mini-pills)
 - Ortho Micronor® Tablets*
 - Ovrette® Tablets†
- IUD Progesterone T
- Female condoms
 - *A thin, loose-fitting, and flexible plastic tube that you put inside your vagina. It covers your cervix to block sperm.*
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
 - *This means not having sex during certain times of the month when you might be more likely to get pregnant. It does not work.*
- Withdrawal
 - *Your partner can leak enough sperm to get you pregnant even if he does not come inside you.*
- Cervical shield‡
 - *A silicone disc that sticks to your cervix to keep sperm out.*

Tell your doctor what type of birth control you are using. You will need to change to effective forms if your birth control is listed above. You must use 2 effective forms together all the time for at least 1 month and have a negative pregnancy test.

*Ortho Micronor is a registered trademark of Ortho-McNeil Pharmaceutical, Inc.

†Ovrette is a registered trademark of Wyeth Pharmaceuticals, Inc.

‡ A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception. See page 28.

Ask yourself:

1. Which of the following is NOT one of the effective primary or secondary forms of birth control while taking isotretinoin?
 - A) Partner's vasectomy or tying your tubes (tubal sterilization)
 - B) Natural family planning
 - C) LNg20 IUD
 - D) Cervical cap with spermicide

2. Which of the following are effective forms of birth control for someone on isotretinoin?
 - A) The hormonal skin patch and a male latex condom with spermicide
 - B) Cervical cap and a male latex condom
 - C) Copper T380A IUD and withdrawal
 - D) Birth control pills and a diaphragm with spermicide

Answer key: page 38



WHY DO I NEED HELP CHOOSING BIRTH CONTROL?

Not every birth control form is good for everyone. Some female patients should not use certain birth control, such as hormones or an IUD. If you are not good at remembering to take medicines, you should not choose birth control pills. Your dermatologist, gynecologist, or family doctor will help you choose the right forms for you. They will also give you exact instructions on how to use them.

Choose forms that you will actually use all the time. Some female patients have found it hard to use 2 forms of birth control together all the time. **This workbook will help you sort through these questions.** It will help you choose the 2 birth control forms that will be best for you. Here are some questions to think about.

Ask yourself:

- Have you ever used birth control? Did you think you will need to use birth control someday?
- What birth control are you using now? Do you like it and want to continue using it? Is it on the list of effective birth control for the iPLEDGE program?
- Are you currently having sex?
- Are you ever pressured into sex or think you may be forced to have sex?
- If you are taking birth control pills, do you ever forget to take them? Do you ever take them out of order? Do you always take medications the way you are told?
- Are there any forms of birth control you have heard about and would like to try?
- Can you rely on your partner's cooperation when using birth control, such as getting him to use a male latex condom each time you have sex?
- Are you worried about protecting yourself from STDs (sexually transmitted diseases) or HIV (AIDS)?
- Is the cost of birth control a problem for you?
- Do you mind having to stop sex play to use a male latex condom or diaphragm?
- Do you worry about certain forms of birth control?
- Do you ever want to be pregnant?

> What If I Cannot Use 2 Forms Of Birth Control Together All The Time?

Talk with your dermatologist, gynecologist, or family doctor. See if you cannot find a way to use 2 forms of effective birth control during this time. If you plan to have sex during your treatment and feel you cannot be 100% successful in using 2 forms of birth control each time, you should not take isotretinoin.

> What If My Birth Control Fails?

The section on “Emergency Birth Control (Emergency Contraception)” is on page 31 of this workbook. It tells you what emergency birth control is and where to get it quickly.



MAKING A CHOICE ABOUT BIRTH CONTROL

> General Advice

Stay with your current primary form of birth control if:

- You are currently using an effective primary form AND you use it perfectly. For example, you do not miss birth control pills or hormone shots.
- You are satisfied with it.

Talk with your dermatologist, gynecologist, or family doctor about changing birth control before you start isotretinoin treatment if you:

- Do not use your current form of birth control perfectly. For example, you forget to change hormonal skin patches every week.
- Are not satisfied with the birth control you are using now. Changing birth control in the middle of your isotretinoin treatment is difficult.

You need to tell the doctor who prescribes your isotretinoin if you decide to change forms of birth control during treatment. You may have to stop having sex until your new form of birth control is working. You may have to stop isotretinoin and wait until you have been using the new form with a second form for at least 1 month and have a negative pregnancy test.

> Planning Ahead With Your Partner

You want your partner to support you as you go through isotretinoin treatment. It is a great idea to talk with him about the iPLEDGE program before you start. Do not surprise him later.

1. Talk to him about why you decided to take isotretinoin at this time.
2. You will want him to agree with and support your decision to have this treatment.
3. Make sure he knows all the facts about isotretinoin and birth defects. Show him the patient information. Your partner needs to understand all the facts about isotretinoin. He needs to be aware of what good it can do, as well as its risks.
4. Make sure he knows you have to use 2 forms of birth control together correctly all the time for at least 1 month before beginning isotretinoin treatment, during treatment for several months, and 1 month after the last dose of isotretinoin.
5. Make sure he is willing to go along with the iPLEDGE program for several months.

You could ask your partner:

1. To help you make a list of questions to ask your doctor
2. To come with you to a doctor's office visit
3. To help you choose the 2 forms of birth control you will be using

Ask yourself:

1. Your doctor tells you that you need to have a pregnancy test before you can fill a prescription. You would:
 - A) Refuse the test because you know you are not pregnant
 - B) Ask your doctor to explain why you need the test
 - C) Go to another doctor to get isotretinoin
2. I need to use 2 separate, effective forms of birth control at the same time while on isotretinoin because:
 - A) There is a high chance for multiple births from taking isotretinoin
 - B) There is a very high chance that my baby will be deformed if I get pregnant
 - C) I may find it hard to not have sex during treatment and 1 month after my last dose
3. You already take birth control pills. If you want to start isotretinoin, you:
 - A) Review this *iPLEDGE Program Birth Control Workbook*, and then get counseling before you choose a second form
 - B) Do not worry about a second form now, because you are not having sex with anyone

Answer key: page 38



PRIMARY FORMS OF BIRTH CONTROL

This section of the workbook provides information about the different forms of primary birth control. It only gives you the most important information you need for the iPLEDGE program. It does not cover all the side effects or other information about these forms. If you want more information, ask your dermatologist, gynecologist, or family doctor. They have more information written for healthcare professionals and for patients.

None of the primary forms protect against sexually transmitted diseases (STDs) or HIV (AIDS).

> Hormonal Birth Control Forms

Hormonal birth control forms include combination birth control pills, the skin patch, shots, under-the-skin implants, and the vaginal ring. They are prescription medicines that prevent pregnancy.

> **Hormonal Combination Birth Control Pills**

Hormonal combination birth control pills are birth control pills you take by mouth every day for 21 days of each monthly cycle or every day of your monthly cycle. This depends on the brand you are using.

Progesterone-only birth control pills (mini-pills), such as Ortho Micronor® Tablets and Ovrette® Tablets, are not acceptable for the iPLEDGE program because they are not effective enough. If you are using these, you will have to choose another primary form of birth control.

Who should not take birth control pills?

You should not use birth control pills if you are over 35; smoke a lot; had blood clots or breast cancer; have a history of heart disease, liver problems, high blood pressure, or diabetes; or are pregnant or nursing.

Why is it important how I take birth control pills?

Birth control pills provide very good protection only if you take them every day and do not miss any pills. If you miss pills, your chance of pregnancy is much greater. Your chance of getting pregnant is higher if you miss pills at the beginning of your cycle or start your pills too late in your cycle. Less than half of all females take their birth control pills as prescribed.

- The most important thing about using birth control pills as your primary form of birth control is taking them every day to keep the chance of pregnancy as low as possible. If you have not used them perfectly, you may need to choose another primary form of birth control, such as the hormonal shot, an IUD, or a hormonal skin patch.
- Isotretinoin may make birth control pills less effective. That means you could be more likely to get pregnant while you are taking isotretinoin, particularly if you miss a pill.

Are you taking birth control pills now?

If you are, is this going to be your primary form of birth control? Before you decide, ask yourself:

- Do you ever have pills left at the end of the month?
- How often do you miss more than 1 pill per cycle? Do you do it more than 2 cycles in a year?
- Have you ever taken birth control pills out of order?

If you answered yes to any of these questions, you probably need to choose another primary form of birth control.

If you are not taking birth control pills now, why do you think you want to try them? Ask yourself:

- Have you ever had to remember to take a pill every single day?
- Why do you think you can remember this task?

If you do not remember to take your pill every day without fail or have never taken pills every day before, you should probably not use birth control pills during isotretinoin treatment.

Advantages

- You may be able to get pregnant within 3 months after stopping birth control pills.

Disadvantages

- Birth control pills do not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
 - If you skip pills, your chance of pregnancy is very high.
 - Isotretinoin, antibiotics, and St. John's Wort may make birth control pills less effective.
-

What should I do if I miss birth control pills when I am on isotretinoin?

If you miss any birth control pills, do not have sex for the rest of your cycle. You could get pregnant.

- If you miss 1 pill, take it as soon as you remember. Continue taking your other pills at the regular time.
- If the whole day goes by before you realize you missed a pill, it is OK to take 2 pills together.
- **If you miss more than 2 days, you should call your doctor as soon as you realize it.** You are at a greater chance for pregnancy if you start a cycle late or miss taking pills during the first week of each cycle.

Ask yourself:

1. If your 2 birth control forms are birth control pills and the diaphragm with spermicide, and you forgot to take 2 pills in a row, you should:
 - A) Not worry because you are using a diaphragm with spermicide, too
 - B) Not have sex and call your doctor because you do not have enough protection to keep from getting pregnant
 - C) Take birth control pills 2 at a time until you catch up

2. You are talking to your doctor about having your second pregnancy test, so you can start isotretinoin. You have been on birth control pills for 1 month, and it is the second day of your period. Three days ago, you and your partner forgot to use a male latex condom when you had sex. You should:
 - A) Have the pregnancy test anyway because it will tell you if you are pregnant
 - B) Not worry because you have your period
 - C) Tell the doctor you and your partner forgot to use a male latex condom once
 - D) Not worry because you forgot before and never got pregnant

Answer key: page 38

➤ **Hormonal Skin Patch**

The hormonal skin patch is a thin, plastic patch that you put on your skin. It releases female hormones into your body to protect against pregnancy.

Who should not use the hormonal skin patch?

You should not use the patch if you are over 35; smoke a lot; had blood clots or breast cancer; have a history of heart disease, liver problems, high blood pressure, or diabetes; or are pregnant or nursing.

How do I use the hormonal skin patch?

You put a new patch on each week for 3 weeks. The fourth week is patch free, usually the time that you have a menstrual period. You place the hormonal skin patch where you can check it easily—on the upper outer arm, stomach, or upper body—but NOT on your breasts.

Are you using the hormonal skin patch now?

If you are, is this going to be your primary form of birth control? Before you decide, ask yourself:

- Do you have trouble remembering to change the patch each week? Has the patch ever come loose or fallen off and you did not immediately put on another one?
- Have you gained weight so that you weigh close to or more than 200 pounds?

If you answered yes to any of these questions, talk with your dermatologist, gynecologist, family doctor, or birth control counselor. Another primary form of birth control may be better for you.

- If you are not using the hormonal skin patch, why do you think you would change to it?

Advantages

- It is not necessary to remember to take a daily pill. Many female patients have more regular, lighter, and shorter menstrual periods.

Disadvantages

- The patch does not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - If it becomes loose or falls off for more than 24 hours, you can get pregnant.
 - If you leave the same patch on more than 1 week, you can get pregnant.
 - Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
 - Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective.
-

> Hormonal Vaginal Ring

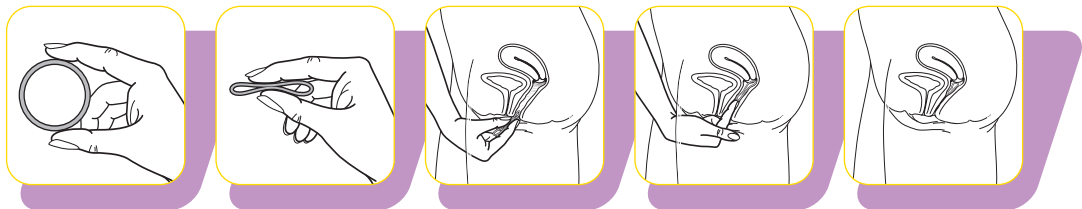
The hormonal vaginal ring is a small flexible ring that you put into your vagina once a month. It releases female hormones into your body and works like birth control pills.

Who should not use the hormonal vaginal ring?

You should not use the hormonal vaginal ring if you are a heavy smoker; over 35; had blood clots or breast cancer; have a history of heart disease, liver problems, high blood pressure, or diabetes; or are pregnant or nursing.

How do I use the hormonal vaginal ring?

You put a new ring in your vagina once every 4 weeks on the same day of the week. You leave it there for 3 weeks and then take it out. During the one-week break, you usually have a menstrual period. **If the ring slips out of the vagina during the 3-week period, you must replace it within 3 hours.**



Are you using the hormonal vaginal ring now?

If you are, is this going to be your primary form of birth control?
Before you decide, ask yourself:

- Do you have trouble remembering to remove the ring after 3 weeks?
- Has the ring ever slipped out and you did not notice?
- Do you have trouble inserting the ring?

If you answered yes to any of these questions, talk with your dermatologist, gynecologist, family doctor, or birth control counselor. Another primary form of birth control may be better for you.

- If you are not using a hormonal vaginal ring, why do you think you would change to it?

Advantages

- It is not necessary to remember to take a daily pill.
 - It does not need to be fitted by a doctor.
 - Many female patients have more regular, lighter, and shorter menstrual periods.
 - Your ability to have children returns quickly after stopping the ring.
-

Disadvantages

- The ring does not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - You cannot use it with a diaphragm or cervical cap.
 - Some medicines for a vaginal yeast infection increase the level of hormones released into the blood.
 - It may irritate the vagina.
 - You may have trouble inserting the ring.
 - Pregnancy can happen if:
 - The unopened package containing the ring is put into direct sunlight or exposed to very high temperatures
 - The ring slips out of the vagina and you do not replace it within 3 hours
 - The ring does not stay in the vagina for 3 weeks
 - You leave the ring in the vagina for more than 3 weeks
 - Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
 - Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective.
-

> Hormonal Shots—Combination Hormones

Combination hormonal shots contain 2 female hormones: estrogen and a progestin. They work like birth control pills to prevent pregnancy.

Who should not use the combination hormonal shots?

You should not use the combination hormonal shots if you are over 35; smoke a lot; had blood clots or breast cancer; have a history of heart disease, liver problems, high blood pressure, or diabetes; or are pregnant or nursing.

How do I take combination hormonal shots?

Your dermatologist, gynecologist, or family doctor can give you a hormonal shot in your arm, belly, or buttocks once every 4 weeks.

Are you taking combination hormonal shots now?

- If yes, is this going to be your primary form of birth control? How often do you miss shots?
- If you are not getting combination hormonal shots, why do you think you would change to them?

Advantages

- A single shot works for 4 weeks at a time.
- There is no daily pill to take.

Disadvantages

- Combination hormonal shots do not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
- Common side effects include breakthrough bleeding, nausea and vomiting, and headaches.
- You must go to your doctor every 4 weeks to get your shot.
- If you are planning to get pregnant AFTER you finish your isotretinoin treatment, it may take up to a year to get pregnant after you stop combination hormonal shots.
- Isotretinoin, antibiotics, and St. John's Wort may make hormonal forms less effective.

How soon does the combination hormonal shot start to work?

It can take up to 1 week to get enough protection, even though the combination hormonal shot starts to work right away. You should use other forms of birth control for the first week.

> Hormonal Shots—Single Hormone

Single hormonal shots use a progestin (a female hormone) to prevent pregnancy. They keep you from releasing eggs, keep eggs from growing in the uterus, and make it harder for sperm to get to an egg.

Who should not take single hormonal shots?

You should not take single hormonal shots if you have any unexplained vaginal bleeding, have or had breast cancer, or have liver problems.

How do I take single hormonal shots?

Your dermatologist, gynecologist, or family doctor can give you a shot in your arm, belly, or buttocks once every 12 weeks.

Are you taking single hormonal shots now?

- If yes, is this going to be your primary form of birth control? How often do you miss shots?
- If you are not getting single hormonal shots, why do you think you would change to them?

Advantages

- A single shot works for 12 weeks at a time.
- There is no daily pill to take.
- You can use it if you cannot take the hormone estrogen.

Disadvantages

- Single hormonal shots do not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - They may cause thinning or loss of bone and should not be used for more than 2 years.
 - They may cause irregular bleeding.
 - If you are planning to get pregnant AFTER you finish your isotretinoin treatment, it may take up to a year to get pregnant after you stop getting single hormonal shots.
-

How soon does the single hormonal shot start to work?

If you get the shot within the first 5 days of your menstrual flow, the protection against pregnancy begins right away.

> Hormonal Intrauterine Device (LNg20 IUD)

The hormonal IUD LNg20 is a small piece of plastic your doctor puts into your uterus. The LNg20 IUD has a progestin (female hormone) that keeps you from releasing eggs and slows down sperm.

The Progesterone T IUD is different from the LNg20. The Progesterone T IUD **is not an acceptable primary form of birth control for the iPLEDGE program.** If you are using it, you will have to choose another primary form of birth control.

Who should not use a hormonal IUD?

Some of the reasons women should not use the hormonal IUD include pregnancy; serious pelvic infection; having more than 1 sexual partner; problems with your immune system; leukemia; AIDS; IV drug abuse; cancer of the uterus, cervix, or breast; unexplained bleeding from the vagina; liver disease; and fibroids in the uterus.

How do I use a hormonal IUD?

Your gynecologist or family doctor can put in an IUD for you. It may cause cramping at first. The hormonal IUD can stay in place for up to 5 years. You must check for the IUD strings in the first few months after insertion and after each menstrual period.

Do you have a hormonal IUD now?

If you do, is this going to be your primary form of birth control? First, ask yourself these questions:

- Is the IUD in place? Can you feel the string?
- When did you last have it checked by your clinician? It needs to be checked within 3 months after you had it inserted. It needs to be checked at other times as well, such as after you gain or lose a lot of weight or after childbirth.
- If you are not using a hormonal IUD, why do you think you would change to it?

Advantages

- It is a good choice for long-term birth control (5 years), and you may get pregnant fairly quickly when it is taken out.
- It is a good choice if you are not at risk for STDs (sexually transmitted diseases) and have not had a lot of pelvic infections.

Disadvantages

- An IUD does not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - Side effects may include cramps, heavy and longer menstrual periods, and increased chance of infection.
 - Your body may push out the IUD. This can happen without your knowing it. This occurs mostly during a woman's menstrual period.
 - You must check for the strings to make sure the IUD is in place. If you cannot feel the strings or if you can feel the IUD itself, call your gynecologist.
-

Ask yourself:

1. You have an IUD inserted as your choice for a primary form of birth control. Which of the following can you use as a second form?

- A) Male latex condoms with spermicide
- B) Hormonal shots
- C) Cervical cap without spermicide
- D) Diaphragm with spermicide
- E) Mini-pills (e.g., progesterone-only birth control pills)
- F) All of the above

Answer key: page 38

> **Hormonal Implants (Under-The-Skin)**

Hormone implants are no longer available for new users. If you already have a hormone implant, it can be your primary form of birth control. Contact the healthcare professional who put in the implant. Make sure it will still be working for the entire time up to 1 month after your last isotretinoin dose.

> **Non-hormonal Intrauterine Device (Copper T IUD)**

The Copper T IUD is a thin piece of plastic covered with the metal copper. It prevents pregnancy by slowing sperm down and keeping sperm from getting to the egg.

Who should not use the Copper T IUD?

Some of the reasons you should not use the Copper T IUD include pregnancy; serious pelvic infection; having more than 1 sexual partner; problems with your immune system; leukemia; AIDS; IV drug abuse; cancer of the uterus, cervix, or breast; unexplained bleeding from the vagina; liver disease; and fibroids in the uterus. You cannot use this IUD if you are allergic to copper or have Wilson's disease.

How do I use the Copper T IUD?

Your gynecologist or family doctor can put in an IUD for you. It may cause cramping at first. The Copper T IUD can stay in place for up to 10 years. You must check for the IUD strings in the first few months after insertion and after each menstrual period.

Advantages

- You can use it if you cannot take hormones.
- It is a good choice for long-term birth control (10 years).
- You may get pregnant fairly quickly when it is taken out.
- It is a good choice if you are not at risk for STDs (sexually transmitted diseases) and have not had a lot of pelvic infections.

Disadvantages

- An IUD does not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - Side effects may include cramps, heavy and longer menstrual periods, and increased chance of infection.
 - Your body may push out the IUD. This can happen without you knowing it. This occurs mostly during your menstrual period.
 - You must check for the string to make sure it is in place. If you cannot feel the strings or if you can feel the IUD itself, call your gynecologist.
-

➤ Tying Your Tubes (Tubal Sterilization)

Having your tubes tied (tubal sterilization) is an operation that closes the tubes from the ovaries to the uterus. Sperm cannot get through to the egg.

Who should not have their tubes tied?

- You should not have your tubes tied if you want to get pregnant.
- If you have already had your tubes tied, this is your primary form of birth control while taking isotretinoin. You must also choose either a secondary form of birth control or another primary form.
- If you are thinking about having your tubes tied, here is some information about this very effective but permanent means of birth control.

Advantages

- It is very effective birth control.
- It works immediately after the surgery.

Disadvantages

- Having your tubes tied does not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - If you want to have a child later, it is very difficult to re-open the tubes.
 - It is surgery. You would need to have an operation.
 - It increases the chance of ectopic pregnancy (pregnancy in the tubes) if sperm manage to get through the blocked tubes.
-

> Partner's Vasectomy

A vasectomy is an operation that closes off the tubes that carry a man's sperm. The man's fluid should not have sperm in it after a vasectomy. If a man has sex before his doctor says his fluid has no sperm, the woman could get pregnant.

- If you have *only 1* partner *and* he has had a vasectomy, this can be your primary form of birth control while taking isotretinoin. You must also choose a second form of birth control. It is strongly recommended that you choose another primary form to give you very effective protection against getting pregnant.

If your partner is thinking about a vasectomy, here is some information about this very effective, but permanent, means of birth control.

Advantages

- It is very effective birth control.

Disadvantages

- A vasectomy does not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - If a male wants a child later, it is very difficult to open the tubes again.
 - A vasectomy requires minor surgery.
-

Ask yourself:

- Is this my only sexual partner?

If you said no or if you are not sure, you cannot choose vasectomy as your primary form of birth control.



SECONDARY FORMS OF BIRTH CONTROL

Secondary forms of birth control do not adequately protect against pregnancy if they are the only form used. However, they greatly increase your protection against getting pregnant if you use them along with a primary form every time you have sex. Effective secondary forms of birth control forms include barrier forms (male latex condoms, diaphragms, and cervical caps) and other forms (vaginal sponge). The barrier forms are all used with a spermicide. The vaginal sponge contains spermicide. If a secondary form is your second form of birth control, you must use it every time you have sex with a male. The female condom is not an effective secondary form for the iPLEDGE program.

Always use a spermicide with male latex condoms, diaphragms, and cervical caps.

Ask your doctor, gynecologist, or family doctor to show you how to use secondary forms. Be sure you know how to use them correctly.

Make sure you know exactly how to use these forms of birth control. Know what mistakes people make with secondary forms. These mistakes can get you pregnant.

> Spermicides

Spermicides come in several forms—creams, jellies, foams, and suppositories. You use spermicide 10 to 30 minutes before you have sex—each and every time—whenever the male comes in or near the female patient’s vagina. Your dermatologist, gynecologist, family doctor, or birth control counselor can tell you how to use spermicides with your secondary barrier form.

Some people are allergic to spermicides. If you cannot use a spermicide, you must use 2 primary forms of birth control together.

> Male Latex Condom And Spermicide

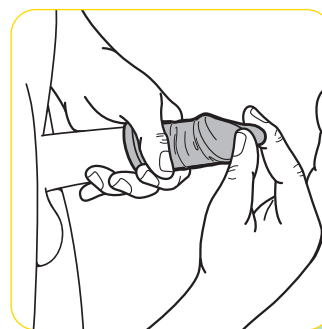
What is a male latex condom?

The male latex condom, also called a “rubber,” is a thin cover put on the male’s penis that traps sperm. You must use them with a spermicide made with water (water-based).

How does my partner use it?

The male latex condom is unrolled on a male’s erect penis as soon as he gets an erection. Waiting too long lets sperm leak out!

You use a spermicide gel, foam, or suppository in your vagina at the same time the male uses the condom.



A male latex condom is good for 1 time only. Do not let your partner try to use it more than once. Oils like petroleum jelly or baby oil can ruin a male latex condom. Safe lubricants include anything made with a water-based gel such as KY Jelly®.

Make sure the male latex condom stays on during sex. If it tears or comes off, call your doctor about emergency birth control.

Choosing a male latex condom as your secondary form

If you choose male latex condoms as a secondary form, your partner must be willing to use a male latex condom each and every time you have sex. Ask yourself:

- Does your sexual partner use a latex condom? Does he have a problem with using a latex condom each time you have sex?
- Does anyone ever force you to have sex if you do not want to?
- Have you and your partner ever forgotten to use latex condoms even when you had meant to?
- Have you ever had sex after drinking when you had not planned to?

Alcohol and drugs can affect your judgment and decisions about having sex.

Male latex condoms may not be the best secondary form for you to choose if:

- Your partner does not want to use them
- You do not like to interrupt sex to let your partner put on a male latex condom
- You have had sex when you did not plan to and did not use birth control

You may want to choose a form you can control or one that you can insert before having sex.

Advantages

- Male latex condoms *do* protect against STDs (sexually transmitted diseases) and HIV (AIDS).
- Male latex condoms are easy to buy, and no doctor's appointment or pelvic exam is needed.
- It is easy to tell when it breaks or slips.

Disadvantages

- Males and females can have a latex allergy.
 - Male latex condoms can break or slip during sex.
 - Many males do not like or want to use them. Your partner has to be committed to using male latex condoms. You are not in control of this birth control form.
 - You must remember to use them every time.
 - You must interrupt sex play to put on a male latex condom.
-

How soon does a male latex condom work?

It works as soon as the male puts it on his erect penis.

Ask yourself:

- Will your partner actually use the latex condom?
 - Did you talk with him about it?
 - Did he agree?
1. Your partner says he is tired of using latex condoms and asks if he can skip it once in a while. Hormonal shots are your primary form of birth control. You should:
- A) Agree to let him just use a condom every other time you have sex
 - B) Tell him to use latex condoms until you get a diaphragm to use
 - C) Tell him that you will not have sex with him unless he uses a latex condom
 - D) Not worry because you have not gotten pregnant yet

Answer key: page 38

> Diaphragm And Spermicide

What is a diaphragm?

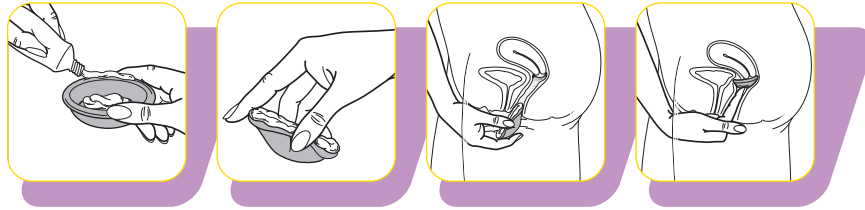
The diaphragm is a shallow latex cup edged with a flexible ring. It covers your cervix and keeps sperm from getting into your uterus. Your gynecologist or family doctor can fit you with one.

Who should not use the diaphragm?

You should not use a diaphragm if you have an allergy to latex or silicone, difficulty putting the diaphragm in, weak vaginal muscles, a history of bladder infections or toxic shock, or had a recent abortion.

How do I use a diaphragm?

You bend the flexible ring and insert the diaphragm into your vagina. The back rim rests below and behind the cervix. The front rim is tucked behind your pubic bone. Before you insert it, you put spermicide in the center of the cup and around the ring.



You can put your diaphragm into the vagina up to 6 hours before sex. You have to leave it in place for at least 6 hours after you have sex. You must put spermicide in the vagina if you have sex again during this time. You should not leave it in for more than 24 hours at a time.

Choosing a diaphragm as your secondary form

Studies have shown that female patients under 30 and female patients who have sex 3 or more times a week have a higher pregnancy rate using diaphragms. If you are in one of these 2 groups, talk with your dermatologist, gynecologist, family doctor, or birth control counselor about whether the diaphragm is right for you.

Have you ever used a diaphragm? What do you like or dislike about the diaphragm?

- Do you find it easy to put it in?
- Have you been using spermicide with the diaphragm?
- Do you find it easy to remember to use it?
- Have you had your diaphragm checked by your gynecologist in the last 2 years to see if it still fits? You must have your diaphragm checked every 2 years, after a gain or loss of 10 pounds, OR after childbirth or an abortion.

If you answered yes to these questions, the diaphragm may be a good secondary form for you.

If you answered no to any of these questions, you should think about another secondary form.

Advantages

- You can easily carry a diaphragm with you and control its use.
 - It is immediately effective.
 - There are no hormones.
 - You do not have to interrupt sex play—it can be inserted before sex.
 - You can use it during your menstrual period.
-

Disadvantages

- A diaphragm does not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - Some female patients have an allergy to latex.
 - Some female patients find it hard to insert.
 - You must put spermicide in your vagina if you have sex again.
 - It can get pushed out of place during sex.
 - It requires a prescription and pelvic exam. A diaphragm lasts about 1 to 2 years.
 - You must check it for holes and tears and clean it after sex.
-

How soon does a diaphragm work?

It works as soon as spermicide is applied and you put it in correctly.

> Cervical Cap And Spermicide

What is the cervical cap?

The cervical cap is a small latex or rubber cup. You use it with spermicide. It covers your cervix so that sperm cannot get in your uterus. It must fit perfectly to work. Your gynecologist or family doctor can fit you for one.

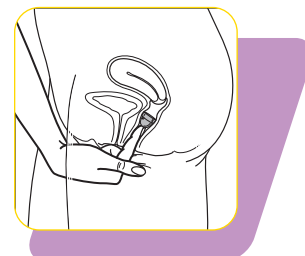
Who should not use a cervical cap?

You should not use a cervical cap if you have an allergy to latex or rubber, a history of pelvic infections, abnormal Pap tests, or Toxic Shock Syndrome (TSS).

How do I use a cervical cap?

The cap is filled one-third full with spermicide. You squeeze it as you put it in your vagina. You press it onto the cervix to cover it completely. You can put the cap in the vagina right before sex, but it stays better if you put it in place 30 minutes before sex. You have to leave it in place for at least 6 hours after you have sex. You can leave in place up to 48 hours.

The cervical cap is made of latex. Never use it with an oil-based lubricant like petroleum jelly. This will destroy the cap.



What is the difference between a diaphragm and a cervical cap?

The cervical cap is a little harder to learn how to use. With a cervical cap, there is no need to insert extra spermicide if you have sex again. You can also leave the cap in place for a longer time—48 hours instead of 24 hours. You cannot use the cervical cap if there is any vaginal bleeding, such as during your menstrual period.

Choosing the cervical cap as your secondary form

Studies have shown that female patients under 30 and female patients who have sex 3 or more times a week have a higher pregnancy rate using the cervical cap. If you are in one of these 2 groups, talk with your gynecologist or family doctor about whether the cervical cap is right for you.

Have you ever used a cervical cap? What do you like or dislike about it?

- Do you find it easy to put in?
- Have you been using spermicide with the cervical cap?
- Do you find it easy to remember to put it in?

If you answered yes to these questions, the cervical cap seems to be a good secondary form for you.

If you answered no to any of these questions, talk with your gynecologist or family doctor before choosing this secondary form.

Advantages

- You can easily carry a cervical cap with you and control its use.
- It is immediately effective.
- It has no hormones.
- There is no interruption of sex play—it can be inserted in advance.

Disadvantages

- A cervical cap does not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - Some female patients have an allergy to latex.
 - Some female patients find it harder to insert than a diaphragm.
 - You cannot use it during your menstrual period.
 - You need a prescription and a pelvic examination to fit a cervical cap.
 - A cap lasts about 1 year.
 - You must check it for holes and tears and clean it after sex.
-

> Vaginal Sponge

What is the vaginal sponge?

The vaginal sponge is a soft foam disc or pillow containing 1 gram of the spermicide nonoxynol-9. Inserting the sponge puts spermicide in your vagina and keeps it there during sex. You insert it in the vagina so it sits over your cervix. It has a string loop attached for easy removal.

Who should not use a vaginal sponge?

Female patients who are allergic to the spermicide nonoxynol-9 should not use the vaginal sponge.

How do I use the vaginal sponge?

First, wash your hands. Wet the sponge thoroughly with clean tap water. Squeeze the sponge gently several times until it is foamy. This releases the spermicide. Pinch the sides of the sponge together. Be sure the string loop is on the underside of the sponge. Squat or sit down, bend your wrist, and push the sponge gently up into your vagina as far as it will go. Check the position of the sponge to make sure the sponge covers your cervix.

How do I take the sponge out?

Wait at least 6 hours after your last sexual activity before taking the sponge out. You can leave it in place for up to 30 hours. You do not need more spermicide if you have sex more than once during that time. To take the sponge out, you need to catch the string loop and gently pull on it.

Choosing the vaginal sponge as your secondary form

Have you ever used a vaginal sponge? What do you like or dislike about it?

- Do you find it easy to put in? Easy to take out?
- Do you find it easy to remember to put it in?

If you answered yes to these questions, the vaginal sponge may be a good secondary form for you.

If you answered no to any of these questions, talk with your gynecologist or family doctor before choosing this secondary form.

Advantages

- You can easily carry a vaginal sponge with you and control its use.
 - It is immediately effective.
 - It has no hormones.
 - There is no interruption of sex play—it can be inserted in advance and is effective for up to 24 hours.
 - No fitting is needed; you can buy it over the counter.
 - It is comfortable and easy to use.
-

Disadvantages

- The vaginal sponge does not protect against STDs (sexually transmitted diseases) or HIV (AIDS).
 - It is not as effective in female patients who have had children.
-



EMERGENCY BIRTH CONTROL (Emergency Contraception)

Emergency birth control is also called “after sex” or “morning after” birth control. It can prevent pregnancy after sex 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 female patient who is sure she is not already pregnant.

There are 2 forms of emergency birth control:

1. Emergency Contraceptive Pills (ECPs)—used within 3 days. ECP is several high-dose birth control pills. You must take the first dose of ECP within 3 days of having sex without enough protection. The sooner you take ECP, the more likely it is to work. The pills can give you severe nausea. Ask your doctor for something to help with the nausea if you need this treatment.
2. Putting in an IUD—used within 5 days. You need to have the IUD inserted within 5 days of having sex without adequate protection.

This form is not good for female patients who have not had a child or are at risk for STDs (sexually transmitted diseases). This includes those with new sex partners, more than 1 partner, or whose partners have other partners, and those who were raped.

When would I need emergency birth control?

Call your doctor or gynecologist about emergency birth control if you had sex without adequate protection, such as:

- You forgot to take 2 or more birth control pills and had sex.
- You had sex without using a second form of birth control.
- You were late for your birth control hormonal shot and had sex.
- Your partner’s condom broke or slipped off.
- Your diaphragm or cervical cap slipped out of place or ripped during sex.

Emergency birth control is meant only for emergencies. It does NOT take the place of your usual 2 forms of birth control. Emergency birth control is not to be used instead of regular birth control.

Where can I get emergency birth control?

You 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)

Whom should I call if I cannot find emergency birth control?

Call the private toll-free Emergency Contraception Hotline at 1-888-NOT-2-LATE (1-888-668-2528). They will ask for your city or ZIP code to help you find emergency birth control near you.

Ask yourself:

1. The right way to use emergency birth control is:
 - A) As a second form of birth control
 - B) If you find a tear in your cervical cap after sex
 - C) If you missed several birth control pills and then have sex
 - D) Only after a positive pregnancy test

Answer key: page 38.



REASONS FEMALE PATIENTS GET PREGNANT

There are many reasons female patients get pregnant when they do not want to. You can avoid most of these.

- They did not avoid sex with a male when they were not using birth control.
- They used a birth control form that did not work very well.
- They did not use birth control all the time and every time they had sex.
- They did not use their birth control the right way.
- They had sex with a male partner when they were not expecting to.
- Their birth control form failed.

For most of the reasons, you can make a choice not to make the same mistake. It is very important that you are careful about birth control. Use your birth control as the iPLEDGE program requires. Do not make mistakes that can lead to unexpected pregnancy.



SEPARATING THE MYTHS FROM THE FACTS

Myths are ideas that many people believe are true, but they are not true. You need to know the facts about sex, birth control, and pregnancy to protect yourself.

MYTH—WHAT YOU HEAR

FACT—WHAT IS TRUE

You cannot get pregnant the first time you have sex.	You can get pregnant any time you have sex.
You cannot get pregnant if you do it standing up.	You can get pregnant in any position.
You will not get pregnant if you do not have an orgasm (come).	You can get pregnant any time you have sex regardless of whether or not you have an orgasm.
Douching keeps you from getting pregnant.	Douching does not prevent pregnancy.
You do not have to use something every time.	You should use birth control every time you have sex.
You will not get pregnant if it is the safe time of the month.	There is no safe time, even for female patients who are regular with their menstrual periods. Your body can change and you could get pregnant.
You will not get pregnant if he pulls out before he comes.	Even if he pulls out, he may leak sperm before he comes and you can get pregnant.
It is safe for me to have sex any time, unless I feel PMS changes or pain near my ovaries.	You can get pregnant any time you have sex, not just when you think you are ovulating (releasing an egg).
You cannot get pregnant if you have not had a menstrual period yet.	Your ovaries release an egg (ovulation) before your first menstrual period. You can get pregnant even the very first time this happens, if you have been having sex.
You cannot get pregnant if you have sex underwater.	You can get pregnant anywhere you have sex.

MYTH—WHAT YOU HEAR

My partner says he is sterile (has no sperm) because he had mumps. He never got anyone else pregnant, so I will not get pregnant.

You cannot get pregnant if you miss only 1 birth control pill.

Sexually active means you have to move during sex. If I do not move, I cannot get pregnant.

I am going through menopause and only get my menstrual period every couple of months.

FACT—WHAT IS TRUE

Mumps rarely causes sterility (no sperm). You can get pregnant if you have sex with a man who has had mumps.

Birth control pills work best when you take them every day. You can get pregnant if you miss even one pill, especially at the beginning of your pill cycle

You can get pregnant any time you have sex, whether you move or lie still.

You can get pregnant until you have missed your menstrual period for 1 year—12 months in a row.

You may have heard or read about something that is not listed here that you think might keep you from getting pregnant. Be sure to ask your dermatologist, gynecologist, or family doctor about any form that you cannot find in this book that you think, or have heard, will keep you from getting pregnant. You can only use the effective forms of birth control for the iPLEDGE program.



SEX, ALCOHOL, AND DRUGS

You have seen this message many times before. Alcohol and drugs can make you unable to use good judgment. While you are taking isotretinoin and for 1 month after your last dose, you need to be able to remember to use 2 effective forms of birth control together each and every time you have sex with a male.

Do not let drugs or alcohol keep you from using your secondary form when you have sex. Use it the right way with spermicide. You need to be in control of yourself so:

- You use your secondary form, OR you get your partner to use a male latex condom
- You use spermicide with any secondary barrier form every time



RECOGNIZING PREGNANCY

If you think you might be pregnant, stop isotretinoin and call your doctor right away. Here are some signs that you might be pregnant:

- You miss your menstrual period.
- You have nausea first thing in the morning.
- Your breasts feel really tender, like at the beginning of a menstrual period.
- The area around your nipples may look darker.
- You feel really tired and want to sleep.
- You feel you have to go to the bathroom a lot.
- You may have spotting of blood at the time of your menstrual period, but no real bleeding.

> Ectopic (Tubal) Pregnancy

Sometimes a baby starts to grow outside the uterus. This is a serious problem. Call your doctor right away, if you have these signs:

- Sudden pain or severe cramping in your lower abdomen
- Bleeding or spotting with abdominal pain after you miss a menstrual period
- Fainting or dizziness lasting more than a few seconds

> Pregnancy Testing

If you have any questions about whether you might be pregnant, talk with your doctor.

[illegible]

NOTES:

[illegible]



Birth Control Information

You can get information about birth control 24 hours a day, 7 days a week on the telephone. Call the toll-free number **1-866-495-0654** to learn about these subjects:

1. Isotretinoin and Birth Defects
2. Sex, Pregnancy, and Birth Control
3. Different Methods of Birth Control
4. Emergency Contraception
5. Pregnancy and Pregnancy Testing

This telephone line is for education only. It does not take the place of talking with your doctor. He or she is the best source of information for you.

Answer Key To Birth Control Questions

Page 8:

- 1. B
- 2. A and D

Page 11:

- 1. B
- 2. B and C
- 3. A

Page 14:

- 1. B
- 2. C

Page 21:

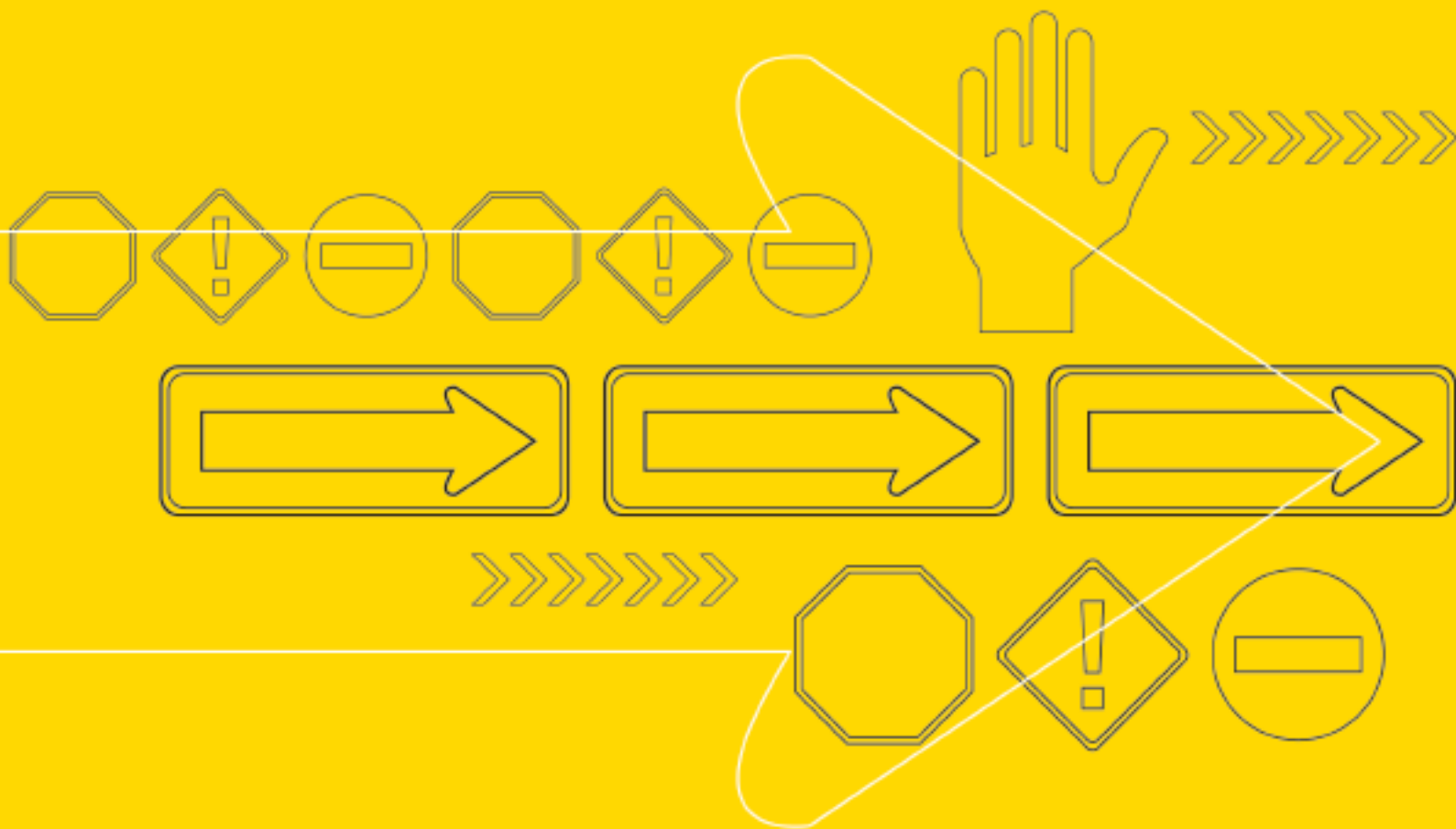
- 1. A and D

Page 26:

- 1. B and C

Page 32:

- 1. B and C



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.

IMPORTANT NOTICE

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

Fill your isotretinoin prescriptions *only* at pharmacies that are licensed in the United States and are registered with and activated in the iPLEDGE program.



iPLEDGETM
Committed to Pregnancy Prevention