

Be Prepared, Be Protected

VIDEO SCRIPT

SCENE 1: ABSTINENCE

FEMALE 1: I thought I was abstinent. I guess I didn't know what abstinence really means. Now I do.

ANNOUNCER: It's important to know what abstinence means. Not having sex. Not once, twice, or ever. Just because you're not having sex now, doesn't mean you will have always be abstinent. You're only abstinent if you know you won't be tempted to have sex. And this becomes especially important when you are taking a drug that may cause birth defects to your unborn baby. Think about it: Are you *really* abstinent?

SCENE 2: UNPREPARED PREGNANCY

FEMALE 2: I can't believe I'm pregnant. It was just that one time. And I have been so careful. This can't be right.

ANNOUNCER: You have to be sure if you are having sex at any time you can't use any excuses. It doesn't matter if your periods are irregular, or if you think you can't get pregnant, or if you don't have sex frequently. And if you are on a medication that could be harmful to your unborn baby, you need to be especially and extremely careful. Once can be enough.

SCENE 3: WITHDRAWAL

FEMALE 3: We used withdrawal for a long time. But this time withdrawal just didn't work.

ANNOUNCER: Withdrawal is unreliable. Use effective birth control such as the contraceptive pill, diaphragm, condom, and if you are taking a medication that may cause birth defects to your unborn baby, use a combination of two. If you don't like the pill, you have other options such as long lasting contraceptive implants, injectables, and intrauterine devices—IUDs. Always practice safe birth control using reliable effective methods to avoid pregnancy.

SCENE 4: BEING UNPREPARED

FEMALE 4: This is so nice. (Thoughts of Female 4) *I didn't think this would happen. I mean at least not tonight. I'm so surprised and unprepared.*

ANNOUNCER: Be prepared and protected. Think about it before hand. You may have sex and you might get pregnant? Don't assume your partner will take responsibility. And if you are on a medication that may cause birth defects—think about your unborn baby. Be prepared and ready to use reliable effective forms of birth control.

SCENE 5: BIRTH CONTROL CAN FAIL

FEMALE 5: I can't believe this. There's a hole in my diaphragm. What if I get pregnant? What am I going to do?

ANNOUNCER: Your doctor or nurse can help you find out if you are really pregnant. If you are, they can give you advice. Always make sure your birth control is reliable and effective. And if you are on a drug that may cause birth defects, be sure you are doubly protected.

If you have any questions you should speak to your doctor or nurse. Carefully follow instructions provided by your prescriber, and consult with them if you have any questions about pregnancy, birth control, or your medical treatment.

[TYPE—NO VOICE]

Frame 1:

Complete Contraceptive Certainty = Be prepared Be protected

Frame 2:

You have just seen five scenarios with the most common reasons women have unwanted or ill-timed pregnancies.

Frame 3:

If you are not being completely abstinent, then

- Use birth control regularly
- Use the most effective types of birth control
- Be sure the method you choose is reliable
- Be prepared and be protected

Current as of 6/1/2013. This document may not be part of the latest approved REMS.

Frame 4:

Brought to you as an educational service.

Opening Segment

“ISOTRETINOIN CANNOT BE TAKEN BY WOMEN WHO ARE PREGNANT, BECAUSE ISOTRETINOIN CAN CAUSE SEVERE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY.

In this video we will see what can happen to an unborn baby if the baby’s mother takes isotretinoin.

A woman must not take isotretinoin at any time during pregnancy.

Storyboard P2

Isotretinoin is usually prescribed for males and females to treat the most severe form of acne called nodular acne. This type of acne cannot be cleared up by any other acne treatments, including antibiotic pills. Nodular acne has many red, swollen, tender lumps that form in the skin. These lumps are the size of a pencil eraser or larger and can result in permanent scars if not treated.

Because of serious side effects and birth defects, patients should use isotretinoin only if other treatments including antibiotic pills have not worked.

Storyboard P3

“FEMALE PATIENTS MUST NOT TAKE ISOTRETINOIN IF THEY ARE PREGNANT, PLAN TO BECOME PREGNANT OR BECOME PREGNANT DURING THERAPY. TO AVOID PREGNANCY, WOMEN MUST USE TWO FORMS OF EFFECTIVE CONTRACEPTION ONE MONTH BEFORE STARTING ISOTRETINOIN, WHILE TAKING ISOTRETINOIN, AND FOR ONE MONTH AFTER STOPPING ISOTRETINOIN UNLESS THEY ARE ABSOLUTELY ABSTINENT, NEVER HAVING SEX, OR HAVE HAD THEIR UTERUS OR WOMB REMOVED”.

Storyboard P4

“ISOTRETINOIN CAPSULES BREAK DOWN IN THE BODY AND THE MEDICINE ENTERS INTO THE BLOODSTREAM

Storyboard P5

“AND THE BLOOD IS CARRIED INTO THE PLACENTA WHERE IT REACHES THE UNBORN FETUS.

The medicine can cause severe birth defects.”

Storyboard P6

“It is highly possible that the unborn baby may die because the baby’s mother took isotretinoin.”

Storyboard P7

“If the fetus lives, as the fetus develops, several birth defects can begin to take place.

These birth defects may be caused by taking isotretinoin during pregnancy”.

Storyboard P8

“One of these birth defects may be abnormal skull development”. “Use of isotretinoin during pregnancy may cause an under development or over development of the skull”.

Storyboard P9

“Development of the ears may also be affected”. “The ears may not fully develop if isotretinoin is used during pregnancy. The outer ear may be deformed and the ear canal may be very small or absent entirely causing deformity”.

Storyboard P10

“The eyes also may not develop fully”.

“The eye socket may be very small or not develop at all causing facial deformity

Storyboard P11

“As face structure begins to form the fetus can have a flattening of the nose and a twisting of the mouth. These birth defects could happen from using isotretinoin during pregnancy”.

Storyboard P12

“The baby may also be born with a separation of the roof of the mouth and sometimes the lips which is known as a cleft palate”.

Storyboard P13

IN ADDITION TO THE VISIBLE DEFECTS, SEVERAL INTERNAL SERIOUS AND LIFE-THREATENING BIRTH DEFECTS MAY DEVELOP IN THE HEART AND IN THE ENTIRE HEART AND BLOOD FLOW SYSTEM.

One of these defects can include an abnormal heart that has the arteries and veins in the wrong position.

Storyboard P14

“The system that helps to fight infection may also be affected. One of the glands in this system - the thymus gland may not develop and the baby then would have trouble fighting infections.” “In addition, another gland -the parathyroid gland may not develop. The parathyroid gland helps the baby to form bones by controlling the amount of calcium in the body.

Storyboard P15

Brain and nervous system defects including an abnormal brain may occur...” OR AN UNDERDEVELOPMENT OF THE BRAIN. IT HAS ALSO BEEN REPORTED THAT SOME CHILDREN HAVE LOW IQ SCORES”.

Storyboard P17

In summary, taking isotretinoin during pregnancy can result in any or all of these birth defects:

The skull may over- or under- develop.

FACIAL DYSMORPHIA CAN OCCUR, CAUSING A FLATTENING OF THE NOSE AND DISTORTION OF FACIAL STRUCTURE.

Enlargement of the brain may occur.

Eye sockets may be very small or not develop at all.

The brain can also under-develop.

Ears may not fully develop.

The thymus gland may not develop, affecting an infant's ability to fight off disease.

Abnormalities in the heart and entire cardiac system can be life threatening.

A cleft palate may form.

Storyboard P18

UNLIKE THE BIRTH DEFECTS THAT ARE SEEN IN THE BABIES WHEN MOTHERS TAKE ISOTRETINOIN, THERE IS NO PATTERN OF BIRTH DEFECTS WHEN FATHERS TAKE ISOTRETINOIN.

“But men who take isotretinoin should be careful in other ways.” Men might not realize that they should not donate blood during, and for a period of one month following, the end of their isotretinoin treatment”.

Storyboard P19

“As discussed earlier, isotretinoin is carried through the bloodstream and a pregnant woman could, unknowingly accept a blood transfusion from a man or a woman who took isotretinoin. The blood and medicine could then pass into the placenta possibly harming an unborn baby”.

Therefore, it is extremely important that both men and women taking isotretinoin do not donate blood during treatment and for a period of at least one month following the end of their isotretinoin treatment.

Storyboard P 20

“Neither men nor women should *ever* share their isotretinoin with another woman...”

Storyboard P 21

“...BECAUSE OF THE RISK THAT SHE MAY BE PREGNANT.”

“No one should ever share any medicine with anyone else, because the medicine may harm the other person.”

Black Box

YOU MUST NOT BECOME PREGNANT WHILE TAKING ISOTRETINOIN, OR FOR ONE MONTH AFTER YOU STOP TAKING ISOTRETINOIN.

Isotretinoin can cause severe birth defects in babies of women who take it while they are pregnant, even if they take isotretinoin for only a short time.

There is an extremely high risk that your baby will be deformed or will die if you are pregnant while taking isotretinoin. Taking isotretinoin also increases the chance of miscarriage and premature births.

Female patients will not get their first prescription for isotretinoin unless there is proof they have had two negative pregnancy tests. The first test must be done when your prescriber decides to prescribe isotretinoin. The second pregnancy test must be done during the first five days of the menstrual period right before starting isotretinoin therapy, or as instructed by your prescriber. Each month of treatment, you must have a negative result from a urine or serum pregnancy test. Female patients cannot get another prescription for isotretinoin unless there is proof that they have had a negative pregnancy test.

WHILE YOU ARE TAKING ISOTRETINOIN, YOU **MUST** USE EFFECTIVE BIRTH CONTROL. **YOU MUST USE 2 SEPARATE, EFFECTIVE FORMS OF BIRTH CONTROL AT THE SAME TIME** FOR AT LEAST ONE MONTH BEFORE STARTING ISOTRETINOIN, WHILE YOU TAKE IT, AND FOR ONE MONTH AFTER YOU STOP TAKING IT. YOU CAN EITHER DISCUSS EFFECTIVE BIRTH CONTROL METHODS WITH YOUR PRESCRIBER OR GO FOR A FREE VISIT TO DISCUSS BIRTH CONTROL WITH ANOTHER PHYSICIAN OR FAMILY PLANNING EXPERT. YOUR PRESCRIBER CAN ARRANGE THIS FREE VISIT, WHICH WILL BE PAID FOR BY THE MANUFACTURER.

You must use two separate forms of effective birth control because any method, including birth control pills and sterilization, can fail. There are only 2 reasons that you would not need to use 2 separate methods of effective birth control:

1. You have had your womb removed by surgery – a hysterectomy or
2. You are absolutely certain you will not have genital-to-genital sexual contact with a male before, during and for one month after isotretinoin treatment.

IF YOU HAVE SEX AT ANY TIME WITHOUT USING TWO FORMS OF EFFECTIVE BIRTH CONTROL, GET PREGNANT, OR MISS YOUR PERIOD, STOP USING ISOTRETINOIN AND CALL YOUR PRESCRIBER RIGHT AWAY.