

**Project: TRADEMARK Capsules Female Patient Video Script**

**Assignment:** Revamp two video scripts (one for men, one for women) to better explain the risks involved in taking a certain medication and the procedures that must be followed due to the risks.

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**Title:** Important Information for Women Taking TRADEMARK Capsules

<i>Dermatologist comes onscreen. Medium shot; examination room in background</i>	<p>Hello, I'm Dr. [NAME] at [hospital or practice name]. If you're watching this video, it means your doctor has recommended TRADEMARK Capsules as a treatment for your severe psoriasis.</p> <p>TRADEMARK Capsules come with some serious risks — risks you need to fully understand before making the decision to use this medication.</p> <p>Although there have not been any babies with birth defects born to women taking TRADEMARK Capsules, this medication belongs to a class of drugs known as “oral retinoids,” which are known to cause severe birth defects in some fetuses.</p>
<i>Image of baby</i>	<p>There's no real way of knowing which fetus may be affected and which fetus may not be affected, but TRADEMARK Capsules <i>is</i> a “probable teratogen.” What this means is if you become pregnant while taking TRADEMARK Capsules, or even within a month of discontinuing use of this medication, your baby could be born with severe birth defects.</p>
<i>Indicate damage to heart, brain, and nervous system (arrows or other)</i>	<p>Some of these birth defects happen on the inside; in other words, you can't see them, but there can be damage to your baby's brain, as well as to its heart, glands, and nervous system.</p>
<i>Image of baby morphs into image of baby with external defects</i>	<p>TRADEMARK Capsules may also cause birth defects you can see, such as ears that are too low, deformed, or missing; eyes that are too far apart; a flat nose; a larger than normal head; and a chin that is too small.</p>

<p><i>Back to dermatologist</i></p>	<p>TRADEMARK Capsules can also cause birth defects that may cause your baby to die.</p> <p>These birth defects can occur even if you've only taken TRADEMARK Capsules for a short period of time and for up to one month after your treatment with TRADEMARK Capsules is over.</p>
<p><i>Text on screen:</i>  “TRADEMARK Capsules should NEVER be used...”</p>	<p>That's why TRADEMARK Capsules should NEVER be used by a woman who is pregnant, currently breastfeeding, or who becomes pregnant while taking this medication.</p> <p>In other words, if you are currently pregnant, breastfeeding, or are thinking about becoming pregnant any time soon, do not consider TRADEMARK Capsules for treating your psoriasis.</p>
<p><i>Back to dermatologist</i></p>	<p>If, however, you have no plans to become pregnant while undergoing treatment with TRADEMARK Capsules, <i>it is absolutely vital that you understand the responsibilities that go along with this treatment.</i></p> <p>The MOST important responsibility for you is to not become pregnant while you are taking TRADEMARK Capsules.</p> <p>Even before you begin your first course of treatment with TRADEMARK Capsules, your doctor will do two pregnancy tests about one month apart to be sure that you're not pregnant. The second pregnancy test must be performed in a laboratory that you will be sent to by your physician.</p>
<p><i>Text on screen:</i>  “To obtain a new thirty-day supply:”</p> <p>“[Check Mark] Laboratory-based pregnancy test”</p> <p>“[Check Mark] Knowledge, attitudes, and behaviors test”</p>	<p>Each prescription you receive will be for only a thirty days' supply — 30 pills — of TRADEMARK Capsules. This is a <i>non-refillable</i> prescription, which means you will have to obtain a new prescription each month.</p> <p>Before your doctor can prescribe a refill for TRADEMARK Capsules each month, you'll need to take a laboratory-based pregnancy test to make sure you're not pregnant.</p> <p>You'll also be asked to complete a knowledge, attitudes, and behaviors test. The purpose of this test is to make sure you really understand the risks to unborn children associated with taking this medication and the importance of using effective birth control.</p>

<p><i>Back to dermatologist</i></p>	<p>A final pregnancy test will be performed thirty days after you stop taking TRADEMARK Capsules. It is <i>only after</i> you have this last pregnancy test that you can safely attempt to get pregnant if you wish.</p> <p>Your doctor will also ask you to sign a consent form saying that you will use either two primary methods of birth control or a primary method and a barrier method together.</p> <p>I realize you might not be accustomed to discussing contraception with a doctor other than your gynecologist, and you might feel a little uncomfortable about it.</p> <p>However, considering the risks for a baby if you get pregnant while taking TRADEMARK Capsules, your doctor must make sure you understand this very serious responsibility — and are willing to follow the program to prevent pregnancy.</p> <p>Here’s a little more information about primary and barrier methods of birth control:</p>
<p><i>List primary on left</i></p>	<p>Primary methods of birth control include the Pill, hormone implants, a hormonal vaginal ring or skin patch, an intrauterine device or sterilization, such as a vasectomy or tubal ligation.</p>
<p><i>Build list of barrier on right</i></p>	<p>Barrier methods of birth control include a latex condom for your partner or a diaphragm or cervical cap for you. For barrier methods to be effective you must use a spermicide, which is a cream or ointment that kills sperm.</p>
<p><i>Text on screen:</i> “You must consent to use two effective methods...”</p>	<p>You must use two effective methods of birth control <i>every time</i> you have sexual contact with a man for one month before taking TRADEMARK Capsules, while you are taking them, and for one month after you stop taking TRADEMARK Capsules.</p>
<p><i>Back to dermatologist</i></p>	<p>Even if you plan to avoid sex, you <b>MUST</b> still use two effective forms of birth control in case of a “slip-up” or lapse in abstinence. At least one of these two methods must be a <b>PRIMARY</b> method. The second may be another primary or a barrier method.</p> <p>This may seem like a big commitment, and a lot to ask of yourself — and your partner. But considering the risks to unborn children associated with taking this medication, it’s extremely important that you prevent any pregnancy.</p>

	<p>The fact is, if you're not willing to commit to this, your doctor cannot prescribe TRADEMARK Capsules for you.</p>
<p><i>Show this section of the Patient Guide to TBD Plan</i></p>	<p>All of these birth control methods — and how to use them — are explained in detail in the <i>Information for Women Who Can Have Children</i> section of the <i>TRADEMARK Capsules Patient Guide to TBD Plan</i>, which you may have already received from your doctor.</p>
<p><i>Show montage of brochures and forms for female patients</i></p>	<p>Your doctor can help you get more information on birth control, should you decide to use TRADEMARK Capsules to treat your psoriasis. He or she can also provide you with the name of a family-planning expert who can personally help you in learning more about these birth control methods and in making decisions on what to use.</p> <p>If your own insurance company won't cover the cost of your visit to a family-planning expert, the makers of TRADEMARK Capsules will.</p>
<p><i>Back to dermatologist</i></p>	<p>So what happens if you don't use two forms of effective birth control or if one of those methods fails; for instance, the condom breaks? Emergency contraception, also known as the "morning after" pill, is available to you.</p> <p>Emergency contraception is just that —for emergencies only. It should NOT be considered a primary form of birth control.</p> <p>Also keep in mind that emergency contraception must be used within 72 hours of your having sex. Call your doctor as soon as possible after the contact so he or she can call in a prescription for you.</p>
<p><i>Show number and URL onscreen</i></p>	<p>If you can't get in touch with your doctor, call the emergency contraception phone number: 1-888-NOT-2-LATE, or log on to the Web site at <a href="http://www.not-2-late.com">www.not-2-late.com</a>.</p> <p>This information is also listed on the front of the <i>TRADEMARK Capsules Patient Guide to TBD Plan</i>.</p>
<p><i>Back to dermatologist</i></p>	<p>What if you do become pregnant while taking TRADEMARK Capsules? First you should discuss the risks of continuing the pregnancy with the doctor who prescribed the medication to you, as well as with your own gynecologist or obstetrician.</p>

<i>Show number and PER onscreen</i>	Whether or not you decide to continue the pregnancy, you should call 1-800-XXX-XXXX or your doctor to enroll in the Pregnancy Exposure Registry for follow-up information.
<i>Back to dermatologist</i>	<p>If you decide you would like to use TRADEMARK Capsules, there are a few other <i>very important responsibilities</i> to keep in mind.</p> <p>Your doctor has prescribed TRADEMARK Capsules to you, and <i>only you</i>.</p>
<p><i>Text on screen:</i> “Do not share...”</p> <p>“Not indicated for the treatment of acne”</p> <p>“Do not donate blood...”</p> <p>“Keep TRADEMARK Capsules away...”</p>	<p>This means that as with any other prescription medication, you must never share TRADEMARK Capsules with anyone even if they have symptoms that are similar to yours, even if you are certain they have severe psoriasis.</p> <p>TRADEMARK Capsules are indicated for the treatment of severe psoriasis. The safety and efficacy of TRADEMARK Capsules in the treatment of acne have not been established.</p> <p>You must also not donate blood while taking TRADEMARK Capsules, and for at least one month after you stop taking them. If your blood goes to a pregnant woman, her baby could have the birth defects we discussed earlier.</p> <p>And as with any medication, keep TRADEMARK Capsules away from children.</p>
<i>Back to dermatologist</i>	One other thing to keep in mind is that some patients taking TRADEMARK Capsules or medications similar to TRADEMARK Capsules have reported some serious side effects, such as:
<i>List effects on screen</i>	<ul style="list-style-type: none"> <li>- Depression or feelings of aggression</li> <li>- Changes in the bones or joints</li> <li>- Aches or pains in the bones, joints, muscles, or back</li> <li>- Trouble moving or loss of feeling in their hands or feet</li> <li>- Higher blood sugar levels; in other words, hyperglycemia</li> <li>- Higher blood triglyceride levels, or hypertriglyceridemia</li> <li>- Liver problems</li> <li>- Allergic reactions such as hives, swelling of the mouth or face, or trouble breathing</li> </ul>

<p><i>Back to dermatologist</i></p>	<p>These side effects happen in only a small number of patients, but they may lead to more serious health problems if not treated.</p>
<p><i>Text on screen:</i>  “Tell your doctor if...”</p>	<p>Be sure to tell your doctor if you currently have any major health problems, any history of depression, high cholesterol, hyperlipemia, osteoporosis, weak bones, diabetes, a history of hypertriglyceridemia, or high triglycerides, or have a family history of any of these conditions.</p> <p>If you decide to use TRADEMARK Capsules to treat your psoriasis, he or she will monitor you for any changes associated with these conditions.</p> <p>Also be sure to tell your doctor about any medicines, vitamins, or herbs you are taking.</p>
<p><i>Back to dermatologist</i></p>	<p>Ultimately the decision to take TRADEMARK Capsules is yours alone. Understanding the risks and responsibilities and following all the instructions your doctor provides can help ensure the safe use of TRADEMARK Capsules.</p> <p>Carefully read all the information your doctor gives you. Feel free to ask for a copy of this video to review at home, by yourself or with your partner.</p> <p>And if you have any questions at all regarding TRADEMARK Capsules, talk to your doctor before you begin this treatment. He or she is there to support you and to help you understand the risks and responsibilities of this therapy.</p> <p>You may also call the TBD Plan Call Center at 1-800-####-#### for answers to any questions you have about the use and risks of TRADEMARK Capsules.</p>