SERIOUS TREATMENT
SERIOUS DECISIONS

DO YOUR P.A.R.T.™

Pregnancy Prevention Actively Required During & After Treatment

SORIATANE
(acitretin) Capsules
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CONTRAINDICATIONS AND WARNINGS: SORIATANE® (acitretin) must not be used by females who are pregnant or who may become pregnant during therapy or at any time for at least 3 years after discontinuation of treatment. SORIATANE also must not be used by females of reproductive potential who may not use 2 effective forms of contraception (birth control) simultaneously for at least 1 month before, during, and for at least 3 years after treatment. Two effective forms of contraception (birth control) are to be used simultaneously, even when 1 form is a hormonal contraceptive. Patients should not self-medicate with St. John’s wort because of a possible interaction with hormonal contraceptives. Prescribers must obtain negative results for 2 pregnancy tests before initiating treatment with SORIATANE. The first test is a screening test; the second is a confirmation test done during the first 5 days of the menstrual period immediately preceding therapy with SORIATANE. For patients with amenorrhea, the second test should be done at least 11 days after the last act of unprotected sexual intercourse. If the second pregnancy test is negative, initiation of treatment with SORIATANE should begin within 7 days of the specimen collection. SORIATANE should be limited to a monthly supply. Pregnancy testing throughout the treatment course should be monthly. Females must sign a Patient Agreement/Informed Consent for Female Patients form about the risks of birth defects. Acitretin is a metabolite of etretinate and major fetal abnormalities have been reported with both drugs. Acitretin can interact with ethanol to form etretinate. Therefore, females of reproductive potential must not ingest ethanol during treatment and for 2 months after cessation of treatment. Before prescribing, please see complete pregnancy warning in the accompanying complete prescribing information. Females who have undergone treatment with TEGISON® (etretinate) must continue to follow the contraception requirements for TEGISON.

Less frequent, but potentially serious, adverse events include hepatotoxicity, pancreatitis, and pseudotumor cerebri (please see WARNINGS in complete prescribing information), as well as hyperostosis, alterations in lipids, possible cardiovascular effects, ophthalmologic effects, capillary leak syndrome, and exfoliative dermatitis/erythrodema.
INTRODUCTION

ABOUT SORIATANE
SORIATANE® (acitretin) is a medicine used to treat severe forms of psoriasis in adults. Psoriasis is a skin disease that causes cells in the outer layer of the skin to grow faster than normal and pile up on the skin’s surface. In the most common type of psoriasis, the skin becomes inflamed and produces red, thickened areas, often with silvery scales. Because SORIATANE can have serious side effects, you should talk with your prescriber about whether the possible benefits of SORIATANE outweigh its possible risks.

In women of childbearing potential, SORIATANE should be reserved for non-pregnant patients who are unresponsive to other therapies or whose clinical condition contraindicates the use of other treatments (see boxed CONTRAINDICATIONS AND WARNINGS — SORIATANE can cause severe birth defects).

Most patients experience relapse of psoriasis after stopping therapy. Subsequent courses, when clinically indicated, have produced efficacy results similar to the initial course of therapy.

ABOUT THE DO YOUR P.A.R.T.™ PROGRAM

This program applies to you because your doctor has prescribed SORIATANE for you. This program is for women of childbearing potential.

SORIATANE can cause severe birth defects during treatment and for up to 3 years after a patient stops SORIATANE. The Do Your P.A.R.T.™ program is intended to help you avoid getting pregnant during this time.

The SORIATANE Do Your P.A.R.T.™ Program contains several important components:

- This booklet
- Patient Agreement/Informed Consent for Female Patients form
- Contraception Counseling Referral Program form (optional)
- A Medication Guide for Patients
- Authorization for Use or Disclosure of Health Information
- Voluntary Patient Survey
- Patient Survey Brochure
- Patient Survey Registration Form

Read and complete all of these materials before taking SORIATANE, and be sure to ask your doctor about any questions you have.

YOUR SEXUAL PARTNER

It is strongly recommended that your sexual partner read this booklet in order to understand all of the facts about the risks of birth defects for women taking SORIATANE. It is critical that you and your sexual partner know that you must not become pregnant during or within 3 years after you stop using SORIATANE.
GENERAL INFORMATION

WHAT IS SORIATANE?

SORIATANE is a medicine used to treat severe forms of psoriasis in adults. Psoriasis is a skin disease that causes cells in the outer layer of the skin to grow faster than normal, creating a “traffic jam” of skin cells on the surface. The skin becomes red, irritated, inflamed, thicker, and sometimes has a silvery appearance.

Because SORIATANE can have serious side effects, you should talk with your doctor to see if it is right for you.

SORIATANE might not work right away. It might take 2 or 3 months before your skin may begin to improve.

Psoriasis gets worse for some patients when they first start taking SORIATANE.

SORIATANE has not been studied in children.

Please see the enclosed Medication Guide for Patients for additional information about SORIATANE.

You may also ask your doctor to provide you with the complete prescribing information (package insert) for SORIATANE® (acitretin).

WHAT SHOULD I AVOID WHILE TAKING SORIATANE?

- Do not get pregnant during therapy and for 3 years after treatment discontinuation (SORIATANE can cause birth defects).
- Do not breastfeed.
- Do not consume alcohol (women of reproductive potential only).
- Do not donate blood during therapy and for 3 years after treatment discontinuation. Other women who could get pregnant must not receive blood from patients being treated with SORIATANE.
- Do not share SORIATANE with anyone, even if they have the same symptoms.
- Avoid night driving if you develop any sudden vision problems.
- Avoid nonmedical ultraviolet (UV) light.
- Avoid dietary supplements containing vitamin A.
- Avoid progestin-only birth control pills (“minipills”).

WHAT ARE THE POSSIBLE SIDE EFFECTS OF SORIATANE?

SORIATANE can cause birth defects. Refer to the enclosed Medication Guide for Patients and see “What is the most important information I should know about SORIATANE?” and “What are the important warnings and instructions for females taking SORIATANE?”

Psoriasis gets worse for some patients when they first start treatment with SORIATANE. Some patients have more redness or itching. If this happens, tell your prescriber. These symptoms usually get better as treatment continues, but your prescriber may need to change the amount of your medicine.

Serious side effects. These do not happen often, but they can lead to permanent harm, or rarely, to death. Stop taking SORIATANE and call your prescriber right away if you get the following signs or symptoms:

- Yellowing of your skin or the whites of your eyes, nausea and vomiting, loss of appetite, or dark urine. These can be signs of serious liver damage.
- Bad headaches, nausea, vomiting, blurred vision. These symptoms can be signs of increased brain pressure that can lead to blindness or even death.
- Vision Problems. Decreased vision in the dark (night blindness). Since this can start suddenly, you should be very careful when driving at night. This problem usually goes away when treatment with SORIATANE stops. Stop taking SORIATANE and call your prescriber if you develop any vision problems or eye pain.
- Depression. There have been some reports of patients developing mental problems including a depressed mood, aggressive feelings, or thoughts of ending their own life (suicide). These events, including suicidal behavior, have been reported in patients taking other drugs similar to SORIATANE as well as patients taking SORIATANE. Since other things may have contributed to these problems, it is not known if they are related to SORIATANE.
- Aches or pains in your bones, joints, muscles, or back, trouble moving, or loss of feeling in your hands or feet. These can be signs of abnormal changes to your bones or muscles.
- Frequent urination, great thirst or hunger. SORIATANE can affect blood sugar control, even if you do not already have diabetes. These are some of the signs of high blood sugar.
- Shortness of breath, dizziness, nausea, chest pain, weakness, trouble speaking, or swelling of a leg. These may be signs of a heart attack, blood clots, or stroke. SORIATANE can cause serious changes in blood fats (lipids). It is possible for these changes to cause blood vessel blockages that lead to heart attacks, strokes, or blood clots.
- Blood vessel problems. SORIATANE can cause fluid to leak out of your blood vessels into your body tissues. Call your prescriber right away if you have any of the following symptoms: sudden swelling in one part of your body or all over your body, weight gain, fever, lightheadedness or feeling faint, or muscle aches. If this happens your prescriber will tell you to stop taking SORIATANE.
- Serious allergic reactions. See "Who should not take SORIATANE?" in the Medication Guide. Serious allergic reactions can happen during treatment with SORIATANE. Call your prescriber right away if you get any of the following symptoms of an allergic reaction: hives, itching, swelling of your face, mouth, or tongue, or problems breathing. If this happens, stop taking SORIATANE and do not take it again.
- Serious skin problems. SORIATANE can cause skin problems that can begin in a small area and then spread over large areas of your body. Call your prescriber right away if your skin becomes red and swollen.

Vision Problems. Decreased vision in the dark (night blindness).
GENERAL INFORMATION

(inflamed), you have peeling of your skin, or your skin becomes itchy, and painful. You should stop SORIATANE if this happens.

Common side effects. If you develop any of these side effects or any unusual reaction, check with your prescriber to find out if you need to change the amount of SORIATANE you take. These side effects usually get better if the dose of SORIATANE is reduced or SORIATANE is stopped.

• Chapped lips, peeling fingertips, palms, and soles, itching, scaly skin all over, weak nails, sticky or fragile (weak) skin, runny or dry nose, or nosebleeds. Your prescriber or pharmacist can recommend a lotion or cream to help treat drying or chapping.

• Dry mouth

• Joint pain

• Tight muscles

• Hair loss. Most patients have some hair loss, but this condition varies among patients. No one can tell if you will lose hair, how much hair you may lose, or if and when it may grow back. You may also lose your eyelashes.

• Dry eyes. SORIATANE may dry your eyes. Wearing contact lenses may be uncomfortable during and after treatment with SORIATANE because of the dry feeling in your eyes. If this happens, remove your contact lenses and call your prescriber. Also read the section about vision problems under “Serious side effects”.

• Rise in blood fats (lipids). SORIATANE can cause your blood fats (lipids) to rise. Most of the time, this is not serious. But sometimes the increase can become a serious problem (see information under “Serious side effects”). You should have blood tests as directed by your prescriber.

These are not all the possible side effects of SORIATANE. For more information, ask your prescriber or pharmacist.

SORIATANE CAN CAUSE SEVERE BIRTH DEFECTS.

If you are a woman who could possibly become pregnant, and you and your doctor think that SORIATANE is right for you, there are very important things to understand before starting SORIATANE.

1. You MUST NOT get pregnant while taking SORIATANE. You MUST have 2 negative pregnancy tests before starting SORIATANE. You MUST start treatment with SORIATANE within 7 days of the specimen collection. You MUST have a pregnancy test each month before receiving the next month’s prescription and every 3 months for 3 years after discontinuation.

You MUST use 2 forms of birth control starting 1 month before treatment, the whole time you are treated with SORIATANE, and for 3 years after you stop taking SORIATANE.

2. If you stop taking SORIATANE, you MUST NOT get pregnant for at least 3 years. Keeping track of this time interval is extremely important.

3. You MUST NOT consume alcohol of any kind while taking SORIATANE, or for 2 months after you’ve stopped SORIATANE.

4. You MUST NOT donate blood during therapy and for 3 years after treatment discontinuation.

5. You MUST sign the Patient Agreement/Informed Consent for Female Patients Form.

IF YOU CANNOT AGREE TO THESE REQUIREMENTS, SORIATANE IS NOT FOR YOU.

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AVOIDING PREGNANCY

IMPORTANT INFORMATION FOR FEMALE PATIENTS

SORIATANE is a very powerful drug, and women must be very careful not to become pregnant. If it is possible for you to become pregnant, and you and your doctor agree on using SORIATANE, you must:

• Before starting SORIATANE, take 2 pregnancy tests proving that you’re not pregnant. The first negative test will start the process, and the second negative test will confirm the results. (Your doctor will tell you when and how to take the tests.) Initiation of treatment with SORIATANE should begin within 7 days of the specimen collection and should be limited to a monthly supply.

• Use 2 forms of birth control at the same time, for at least 1 month before and during your treatment with SORIATANE and for at least 3 years after you stop treatment with SORIATANE. You and your doctor should choose 2 forms of birth control. At least one of the methods must be a primary method.

PRIMARY: (you must choose at least 1 from this list)
- Birth control pills (but not progestin-only "minipills")
- Birth control patch
- Intrauterine device (IUD)
- Injected, implanted, or inserted hormonal birth control products
- Having your tubes tied
- Partner’s vasectomy

SECONDARY: (you may choose 1 from this list to use with primary method)
- Diaphragm with spermicide
- Cervical cap with spermicide
- Condom with or without spermicide
- Vaginal sponge (contains spermicide)

Before you receive your first prescription for SORIATANE, you should have discussed and signed a Patient Agreement/Informed Consent for Female Patients form with your prescriber. This is to help make sure you understand the risk of birth defects and how to avoid getting pregnant. If you did not talk to your prescriber about this and sign the form, contact your prescriber.

WHOM CAN I CONTACT FOR BIRTH CONTROL INFORMATION?

TOLL-FREE NUMBER: 1-800-739-6700

A 24-hour, toll-free, automated birth control counseling line has been set up for you to use.

Remember, calling this number is completely confidential—you will never have to give your name, and you cannot be identified.

A 24-hour, toll-free, automated line is available to all patients on SORIATANE. You can also share this information and phone number with members of your family and your partner.

If you need more information about birth control options, the following sites are available on the Internet:
- Association of Reproductive Health Professionals: www.arhp.org
- Planned Parenthood: www.plannedparenthood.org

If you need more information about drugs and birth defects, the following sites are available on the Internet:
- Organization of Teratology Information Services: www.mothertobaby.org
- Centers for Disease Control and Prevention: www.cdc.gov

If you feel you need to talk to an expert on contraception, a Contraception Counselor can be provided for you free of charge. Please see the Contraception Counseling Referral Form at the back of this booklet for more information.
AVOIDING PREGNANCY

COMMONLY ASKED QUESTIONS

How long do I need to use birth control?
• You need to start using 2 forms of birth control at least 1 month before you begin taking SORIATANE.
• You need to use 2 forms of birth control during your entire treatment with SORIATANE.
• You need to continue to use 2 forms of birth control for 3 years after you stop taking SORIATANE.

If you think you have had unprotected sex or you feel that your contraception has failed while taking SORIATANE:
• Contact your prescriber, women’s health centers, pharmacies, or hospital emergency rooms for information on how to get emergency contraception. A 24-hour, toll-free number (1-800-739-6700) is also available for patients to receive automated birth control and emergency contraception information.

What is "emergency contraception"?
Emergency contraception is an option that can be used if you have had unprotected sex or your birth control method failed while taking SORIATANE (or within 3 years after you stop). "Unprotected" means using fewer than 2 types of birth control, or 1 of the forms you were using failed. Emergency contraception, which includes the "morning-after pill", needs to be used as directed after having unprotected sex.

If you think you’ve become pregnant while taking SORIATANE or within 3 years of stopping:
• Stop taking SORIATANE.
• Call your doctor to tell him/her you might be pregnant.
• Call Stiefel at 1-888-784-3335 (1-888-STIEFEL).
• Or call FDA MedWatch at 1-800-332-1088 (1-800-FDA-1088).

IMPORTANT INFORMATION FOR MALE PATIENTS

Very small amounts of SORIATANE are found in the semen of males taking the medication (1/200,000 of a single 25 mg capsule). Based upon available information, it appears that these small amounts of SORIATANE in semen pose little, if any, risk to an unborn child. Discuss any concerns you may have about this with your doctor.
ADDITIONAL CONSIDERATIONS

What about alcohol?

Alcohol can increase the length of time SORIATANE is stored in a woman’s body, causing the risk of birth defects to last longer than 3 years. It is essential that women of reproductive potential do not drink alcohol during treatment with SORIATANE, or for 2 months after they stop treatment.

Alcohol is in more places than you think. Even small amounts found in cold medicine, or alcohol used in cooking, can make the possibility of birth defects last MUCH longer. Be very careful not to allow any kind of alcohol into your body.

If you have any questions about alcohol and SORIATANE, ask your doctor.

What about breastfeeding?

Do not take SORIATANE if you’re breastfeeding. SORIATANE can pass into your milk and may harm your baby.

What about donating blood?

No person (male or female) should donate blood while taking SORIATANE, or for at least 3 years after stopping therapy. The SORIATANE in your blood, if given to a pregnant woman, could harm her baby. SORIATANE does not affect your ability to receive a blood transfusion.
BIRTH CONTROL METHODS

The following descriptions have been supplied to give you an overview of how each birth control method works in your body. For more information, please ask your doctor, refer to the information included with the individual product, or use the resources listed in the “WHOM CAN I CONTACT FOR BIRTH CONTROL INFORMATION?” section on page 4.

What about MINIPILLS?

Do not use “minipills,” which may not work while you take SORIATANE. Ask your prescriber if you are not sure what type of pills you are using.

PRIMARY METHODS
You must choose at least 1 from the following methods.

BIRTH CONTROL PILLS¹

“The Pill” contains hormones that prevent you from becoming pregnant. These hormones prevent your ovaries from releasing eggs and may also keep sperm from joining with an egg. The Pill is safe and effective for most women, and is taken once daily. The Pill needs to be prescribed by a doctor.

Two kinds are available for most women: one has a combination of hormones, and the other has only one hormone (“minipills”).

Do not use “minipills,” which may not work while you take SORIATANE. Ask your prescriber if you are not sure what type of pills you are using.

Effectiveness: Fewer than 1 in 100 women will become pregnant each year with perfect use. With typical use, 9 in 100 women will become pregnant each year.
**BIRTH CONTROL METHODS**

**BIRTH CONTROL PATCH**

The patch, available by prescription, sends hormones into your body through your skin. These hormones help prevent your ovaries from releasing eggs and may also keep sperm from joining with an egg. A new patch is placed on the skin once a week for three weeks in a row, followed by a patch-free week.

**Effectiveness:** Fewer than 1 in 100 women will become pregnant each year with perfect use. With typical use, 9 in 100 women will become pregnant each year.

**INTRAUTERINE DEVICE**

The intrauterine device (IUD) is placed inside your uterus by a doctor and usually either contains copper or releases hormones. Both kinds of IUDs prevent fertilization by affecting movement of sperm so they can’t join with an egg.

**Effectiveness:** Fewer than 1 in 100 women will become pregnant each year if an IUD is used.
BIRTH CONTROL METHODS

INJECTED, IMPLANTED, OR INSERTED HORMONAL BIRTH CONTROL

There are several different kinds of hormonal birth control that can prevent pregnancy.

**Injected or implanted hormones:** This form is given to you by your healthcare provider at specific time intervals. These hormone shots or implants prevent your ovaries from releasing eggs and may also keep sperm from joining with an egg.

**Injected hormone effectiveness:** Fewer than 1 in 100 women will get pregnant each year with perfect use. With typical use, 6 in 100 women will get pregnant each year.

**Implanted hormone effectiveness:** Fewer than 1 in 100 women will get pregnant each year. It lasts up to 3 years.

**Inserted hormones:** This form is usually called the “vaginal ring,” and you insert it into your vagina. It must be prescribed by your doctor. After being properly inserted, it releases a continuous low dose of hormones into your body. These hormones prevent your ovaries from releasing eggs and may also keep sperm from joining with an egg. The ring remains in the vagina for 3 weeks, and then is removed for 1 week.

**Effectiveness:** Fewer than 1 in 100 women will become pregnant each year with perfect use. With typical use, 9 in 100 women will become pregnant each year.
BIRTH CONTROL METHODS

**TUBAL LIGATION¹ ("HAVING YOUR TUBES TIED") OR YOUR PARTNER’S VASECTOMY¹**

Sterilization of women and men requires operations and are meant to be permanent.

"Having your tubes tied" (or tubal ligation) is intended to block a woman’s fallopian tubes, where sperm would join with an egg. There are different types of sterilization incision methods and a non-incision method (Essure). The non-incision method, Essure, takes about 3 months before it is effective. An x-ray should be performed by your doctor to confirm if the fallopian tubes are fully blocked.

A vasectomy is an operation that permanently disconnects a man’s semen duct, which carries sperm. Vasectomies do not work immediately, and it often takes up to 3 months before all the live sperm are gone. A semen analysis should be performed to confirm if there are no more live sperm.

**Tubal ligation effectiveness:** Approximately 5 in 1,000 women will become pregnant after having a tubal ligation performed with traditional incision methods. Fewer than 3 in 1,000 women will become pregnant after having tubal ligation performed with Essure.

**Vasectomy effectiveness:** 1 in 1,000 men will become fertile again after a vasectomy has been performed.

**CONTINUOUS ABSTINENCE¹**

Continuous abstinence is not having sex play with a partner at all.

**Effectiveness:** When used continuously, abstinence is 100% effective in preventing pregnancy.

**MEDICALLY CONFIRMED MENOPAUSE²**

Menopause is the time at "midlife" when a woman has her last period. It happens when the ovaries stop releasing eggs — usually a gradual process. Sometimes it happens all at once. It is confirmed when a woman has missed her period for 12 consecutive months (which can not be attributed to other causes). Menopause also results in lower levels of estrogen and other hormones.

**Induced menopause** occurs if the ovaries are removed or damaged during surgery, chemotherapy, or radiation therapy. In this case, menopause begins immediately.

**Women reach menopause at different times.** The timing is not related to age at last pregnancy, age of menarche (first period), the birth control pill, breastfeeding, class, fertility patterns, height, having been pregnant, or race.
**BIRTH CONTROL METHODS**

The average age for menopause is 51. If menopause is reached naturally or surgically before the age of 40, it is called early or premature menopause.

Estrogen levels drop very abruptly after induced menopause — when both ovaries are removed surgically or damaged by radiation or chemotherapy.

Women in perimenopause (the period of gradual changes that lead into menopause) have reduced fertility but they are not infertile. Although menstruation may be sporadic, pregnancy can happen. That's why women need to consider birth control during perimenopause.

Only your doctor can confirm that you have reached menopause and do not need to pursue contraceptive options.

**SECONDARY METHODS**

You may choose 1 from these options to use with a primary method. Spermicide must be used with the diaphragm and cervical cap. Spermicide is available in a variety of forms and contains a chemical that prevents sperm from joining with an egg. Spermicide may cause irritation. Changing forms or brands may help. Spermicide is not required with condoms or vaginal sponge.

**DIAPHRAGM**

The diaphragm is a shallow latex cup that you insert into your vagina. You must have a custom fitting from a healthcare professional to obtain a diaphragm.

The diaphragm must be used with spermicide, and must stay in place for 6 hours after sex. If you have sex again or if you have sex more than 6 hours after you put in the diaphragm, more spermicide needs to be inserted deep into your vagina.

The diaphragm should not be left in place longer than 24 hours.

**HYSTERECTOMY**

Hysterectomy is the removal of the uterus. It is major surgery and is not usually used for sterilization. It is used to correct significant medical conditions. Hysterectomy ends menstruation as well as the possibility of pregnancy.

**Effectiveness:** 6 in 100 women will become pregnant each year with perfect use. With typical use, 12 in 100 women will become pregnant each year.
BIRTH CONTROL METHODS

CERVICAL CAP

The cervical cap is very similar to the diaphragm, except that it is smaller and covers only the cervix. You must have a custom fitting from a healthcare professional to obtain a cervical cap.

The cervical cap must be used with spermicide. With each sexual act, check that the cervical cap is still covering the cervix and insert more spermicide deep into your vagina. The cervical cap must stay in place for 6 hours after sex and should not be left in longer than 48 hours.

Effectiveness for women who have never been pregnant or given birth vaginally: 14 in 100 women who use the cervical cap will become pregnant each year.

Effectiveness for women who have given birth vaginally: 29 in 100 women who use the cervical cap will become pregnant each year.

CONDOM

Male condoms are made of latex or plastic and are worn on the penis during intercourse. Condoms prevent pregnancy by preventing sperm from entering the vagina. Condoms are non-prescription and available at drugstores, health centers, or grocery stores.

Effectiveness: 2 in 100 women whose partners use condoms will become pregnant each year with perfect use. With typical use, 18 in 100 women whose partners use condoms will become pregnant each year.

VAGINAL SPONGE

The vaginal sponge is made of plastic foam and contains spermicide. The vaginal sponge should be inserted before intercourse deep into the vagina so that it covers the cervix. The vaginal sponge continuously releases a spermicide and blocks sperm from entering the uterus. The vaginal sponge can be inserted up to 24 hours before intercourse and must stay in place for 6 hours after sex. It should not be left in place longer than 30 hours.

Effectiveness for women who have never given birth: 9 in 100 women will become pregnant each year with perfect use. With typical use, 12 in 100 women will become pregnant each year.

Effectiveness for women who have previously given birth: 20 in 100 will become pregnant each year with perfect use. With typical use, 24 in 100 will become pregnant each year.
PATIENT SELF-EVALUATION

Now that you have read the Do Your P.A.R.T.™ brochure and talked with your doctor about SORIATANE and its risks, please use this self-evaluation exercise to test your understanding of some of the most important points.

Please choose the best answer for each of the following 7 questions.

1. Treatment with SORIATANE requires prevention of pregnancy because:
   a. Severe psoriasis may get worse after pregnancy
   b. SORIATANE can cause birth defects
   c. Psoriasis is more likely in children of psoriasis patients
   d. None of the above

2. Before starting treatment with SORIATANE, it is important to be certain I am not pregnant. To be certain, I must:
   a. Test my urine at home with 2 pregnancy test kits
   b. Have my doctor order 2 pregnancy tests, 2 weeks apart
   c. Have my doctor do a screening test for pregnancy when we decide to treat me with SORIATANE, and then test for pregnancy again during the first 5 days of my period (or at least 11 days after the last time I had sex without birth control) to confirm I am not pregnant
   d. Not have sex for one month

3. I must start using 2 effective forms of birth control:
   a. At least 1 month before starting SORIATANE
   b. At the time I take the first dose of SORIATANE
   c. After my period ends
   d. Now

4. I must continue using 2 effective forms of birth control:
   a. As long as I continue to take SORIATANE
   b. For 1 year after I stop taking SORIATANE
   c. For 3 years after I stop taking SORIATANE
   d. Until menopause

5. True or False? (circle one) T  F
   It is important to avoid alcohol while taking SORIATANE and for 2 months after stopping SORIATANE because alcohol can change SORIATANE into another substance that may also cause birth defects, and that lasts in the body for even longer than SORIATANE.

6. True or False? (circle one) T  F
   A female patient with severe psoriasis has used birth control pills for 7 years after her last child was born and they have worked just fine. She still needs to add a second method of birth control before starting treatment with SORIATANE.

7. True or False? (circle one) T  F
   Avoiding pregnancy during and after treatment with SORIATANE is equally the responsibility of my doctor, my partner, and me.
**PATIENT SELF-EVALUATION**

**ANSWERS**

1. **b**
   While a and c are both true, the reason pregnancy prevention is required is because SORIATANE can cause birth defects which can be severe. SORIATANE stays in the body for a long time, so you should not get pregnant for at least 3 years after stopping treatment. If you think you may want to become pregnant in the near future, you should NOT take SORIATANE.

2. **c**
   When we talk about “2 negative pregnancy tests,” we mean a screening test and then a confirmation test during your period. Both tests must be negative BEFORE starting SORIATANE. It is important to be sure you are not pregnant because SORIATANE could harm your developing baby.

3. **a**
   It is important to be sure you have made the right choice of birth control for you and are comfortable using the 2 forms of birth control. If cooperation from your partner is involved, as with condoms, you need to be certain you both understand and accept the requirement to use condoms every time you have sex. Starting 1 month before SORIATANE also helps ensure you are not pregnant. If you and your doctor have decided SORIATANE is right for you, now is a good time to start using 2 forms of birth control, but you must use them for at least 1 month before starting SORIATANE.

4. **c**
   Because SORIATANE remains in your body for a long time after you stop taking the drug, the risk of birth defects continues and you must not get pregnant for at least 3 years after stopping SORIATANE.

5. **TRUE**
   Even a small amount of alcohol can affect how the body handles SORIATANE.

6. **TRUE**
   Every method of birth control can fail, including birth control pills. Because the risk of birth defects with exposure to SORIATANE is so serious, 2 reliable methods are recommended.

7. **FALSE**
   Only you can truly prevent pregnancy. While your doctor will give you information, refer you to counseling, and encourage you to make the right decision, and your partner’s cooperation and support with birth control methods is essential, the success of pregnancy prevention during and after treatment is your responsibility.

**SCORING:**
7 correct? Well done!

If you got any question wrong, please review the brochure again and make sure you understand. Thank you!

Please be sure to discuss any questions or concerns you may have with your doctor before starting treatment with SORIATANE. Other treatment options should be used if you are not willing or able to take seriously the responsibility for pregnancy prevention and actively follow all recommendations.
YOUR PERSONAL RECORD

NAME: __________________________

You MUST have 2 negative pregnancy tests performed by your doctor that show you are NOT pregnant before starting therapy with SORIATANE.

The first test will be at the time that you and your doctor decide that SORIATANE might be right for you.

1. TEST DATE ____________________ TEST RESULT ____________________

The second test will usually be done during the first 5 days of your menstrual period. If the second pregnancy test is negative, initiation of treatment with SORIATANE should begin within 7 days of the specimen collection. SORIATANE should be limited to a monthly supply.

2. START OF MENSTRUAL PERIOD ____________________

TEST DATE _______________ TEST RESULT ____________________

DATE THERAPY WITH SORIATANE BEGAN ____________________ DATE THERAPY WITH SORIATANE STOPPED ____________________

FOLLOW-UP APPOINTMENTS

DATE _____ TIME__________
DATE _____ TIME__________
DATE _____ TIME__________
DATE _____ TIME__________
DATE _____ TIME__________
DATE _____ TIME__________
DATE _____ TIME__________
DATE _____ TIME__________
DATE _____ TIME__________
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FOLLOW-UP APPOINTMENTS

DATE _____ TIME__________
DATE _____ TIME__________
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DATE _____ TIME__________
DATE _____ TIME__________
DATE _____ TIME__________
DATE _____ TIME__________
IMPORTANT PHONE NUMBERS

BIRTH CONTROL COUNSELING
1-800-739-6700

IF YOU BECOME PREGNANT
1-888-784-3335 (1-888-STIEFEL)

Or
1-800-332-1088 (1-800-FDA-1088)

REFERENCES:


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The SORIATANE® (acitretin)
Do Your P.A.R.T.™ Survey:
A Patient's Guide to Participation

Pregnancy Prevention Actively Required During &
After Treatment
**SORIATANE® (ACITRETIN) DO YOUR P.A.R.T.™ SURVEY: A PATIENT’S GUIDE TO PARTICIPATION**

**Why Should You Participate?**

Your doctor has asked you to participate in the SORIATANE® (acitretin) Survey because you are able to become pregnant and were prescribed SORIATANE.

Your participation will be simple: you will periodically complete a short survey questionnaire while you are taking SORIATANE and for three years after you stop.

Sharing this valuable information on the effectiveness of the SORIATANE Do Your P.A.R.T.™ Program will help other women safely use SORIATANE in the future.

**Your Participation in the Survey**

We will contact you each time the survey is to be completed – you won’t have to remember! You will have the option of completing the survey on paper or via the internet at the SORIATANE® (acitretin) Survey website. Completing the survey will only take a few minutes.

While you are taking SORIATANE, you will be asked to complete a brief survey once every three months.

After you stop taking SORIATANE, you will be asked to complete the survey two times a year for three years.

You will be paid for your time after you complete each survey.

<table>
<thead>
<tr>
<th>SORIATANE SCHEDULE FOR PREGNANCY PREVENTION &amp; SAFE PREGNANCY PLANNING</th>
<th>1 MONTH BEFORE TREATMENT</th>
<th>BEFORE TREATMENT</th>
<th>DURING TREATMENT WITH SORIATANE</th>
<th>2 MONTHS AFTER TREATMENT</th>
<th>3 YEARS AFTER TREATMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 FORMS OF BIRTH CONTROL</td>
<td></td>
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<tr>
<td>2 NEGATIVE PREGNANCY TESTS</td>
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<tr>
<td>ONGOING PREGNANCY TESTS</td>
<td>Each month before receiving prescription and every 3 months for 3 years after stopping treatment</td>
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<tr>
<td>DO YOUR P.A.R.T. SURVEY</td>
<td></td>
<td>A SURVEY EVERY THREE MONTHS</td>
<td></td>
<td>A SURVEY EVERY SIX MONTHS</td>
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<tr>
<td>NO ALCOHOL</td>
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<td>NO BLOOD DONATION</td>
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<td>SIGN INFORMED CONSENT</td>
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</table>
Your Privacy

We understand the importance of your privacy. Your participation in the SORIATANE® (acitretin) Survey is completely confidential. Only the researchers and those working with the researchers managing the survey will know your identity. Your name and contact information will not be shared with others, and the answers you provide will never be identified with you in any presentation of the survey results.

How to Contact Us

If you have questions about the SORIATANE Do Your P.A.R.T.™ survey, please call 1-877-351-5495.

Please see the back of this brochure for phone numbers to report a side effect or pregnancy, or for information about birth control or contraception.

Thank You

Thank you for participating in the SORIATANE Survey. The information you provide will help ensure the safe use of SORIATANE now and in the future.
SORIATANE® (ACITRETIN) DO YOUR P.A.R.T.™ SURVEY: A PATIENT'S GUIDE TO PARTICIPATION

What is the SORIATANE® (acitretin) Do Your P.A.R.T.™ Patient Survey?

The SORIATANE Survey is a short, easy-to-answer questionnaire about your use of SORIATANE, pregnancy prevention and your understanding of the risks associated with using SORIATANE. The questions are very similar to the topics that you have already discussed with your doctor or nurse.

The survey is voluntary, but all women who have the potential to become pregnant while taking SORIATANE and for three years after they stop taking SORIATANE are being asked to participate.

For more information, visit the SORIATANE® (acitretin) Do Your P.A.R.T.™ website at www.soriatane.com.

HELPFUL PHONE NUMBERS:

BIRTH CONTROL COUNSELING:
1-800-739-6700

IF YOU BECOME PREGNANT OR HAVE A SIDE EFFECT FROM TAKING SORIATANE:
1-888-784-3335 (1-888-STIEFEL)
OR
1-800-332-1088 (1-800-FDA-1088)

CAUSES BIRTH DEFECTS
DO NOT GET PREGNANT

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PATIENT AGREEMENT/INFORMED CONSENT
FOR FEMALE PATIENTS
To be completed by the patient* and signed by her prescriber

*Must also be initialed by the parent or guardian of a minor patient (under age 18)
Read each item below and initial in the space provided to show that you understand each item. Do not sign this consent and do not take SORIATANE® (acitretin) if there is anything that you do not understand.

(Patient’s name)

1. I understand that there is a very high risk that my unborn baby could have severe birth defects if I am pregnant or become pregnant while taking SORIATANE in any amount even for short periods of time. Birth defects have also happened in babies of women who became pregnant after stopping treatment with SORIATANE.
INITIAL: __________

2. I understand that I must not become pregnant while taking SORIATANE and for at least 3 years after the end of my treatment with SORIATANE.
INITIAL: __________

3. I know that I must avoid all alcohol, including drinks, food, medicines, and over-the-counter products that contain alcohol. I understand that the risk of birth defects may last longer than 3 years if I swallow any form of alcohol during therapy with SORIATANE, and for 2 months after I stop taking SORIATANE.
INITIAL: __________

4. I understand that I must not have sexual intercourse, or I must use 2 separate, effective forms of birth control at the same time. The only exceptions are if I have had surgery to remove the womb (a hysterectomy) or my prescriber has told me I have gone completely through menopause.
INITIAL: __________

5. I understand that I have to use 2 effective forms of birth control (contraception) at the same time for at least 1 month before starting SORIATANE, for the entire time of therapy with SORIATANE, and for at least 3 years after stopping SORIATANE.
INITIAL: __________

6. I understand that any form of birth control can fail. Therefore, I must use 2 different methods at the same time, every time I have sexual intercourse.
INITIAL: __________

7. I understand that the following are considered effective forms of birth control: Primary: Tubal ligation (having my tubes tied), partner’s vasectomy, birth control pills (not progesterin-only “minipills”), injectable/implantable/insertable/topical (patch) hormonal birth control products, and IUDs (intrauterine devices). Secondary: Condoms (with or without spermicide, which is a special cream or jelly that kills sperm), diaphragms and cervical caps (which must be used with a spermicide), and vaginal sponges (contain spermicide). I understand that at least 1 of my 2 methods of birth control must be a primary method.
INITIAL: __________

8. I will talk with my prescriber about any medicines or dietary supplements I plan to take while taking SORIATANE because certain birth control methods may not work if I am taking certain medicines or herbal products (for example, St. John’s wort).
INITIAL: __________

9. Unless I have had a hysterectomy or my prescriber says I have gone completely through menopause, I understand that I must have 2 negative pregnancy test results before I can get a prescription to start SORIATANE. I understand that if the second pregnancy test is negative, I must start taking my SORIATANE within 7 days of specimen collection. I will then have pregnancy tests on a monthly basis during therapy with SORIATANE as instructed by my prescriber. In addition, for at least 3 years after I stop taking SORIATANE, I will have a pregnancy test every 3 months.
INITIAL: __________

10. I understand that I should not start taking SORIATANE until I am sure that I am not pregnant and have negative results from 2 pregnancy tests.
INITIAL: __________

11. I have received information on emergency contraception (birth control), including information on its availability over-the-counter.
INITIAL: __________

12. I understand that my prescriber can give me a referral for a free contraception (birth control) counseling session and pregnancy testing.
INITIAL: __________

13. I understand that on a monthly basis during therapy with SORIATANE and every 3 months for at least 3 years after stopping SORIATANE, that I should receive counseling from my prescriber about contraception (birth control) and behaviors associated with an increased risk of pregnancy.
INITIAL: __________

14. I understand that I must stop taking SORIATANE right away and call my prescriber if I get pregnant, miss my menstrual period, stop using birth control, or have sexual intercourse without using my 2 birth control methods during and at least 3 years after stopping SORIATANE.
INITIAL: __________

15. If I do become pregnant while on SORIATANE or at any time within 3 years of stopping SORIATANE, I understand that I should report my pregnancy to Stiefel at 1-888-784-3335 (1-888-STIEFEL) or to the Food and Drug Administration (FDA) MedWatch program at 1-800-FDA-1088. The information I share will be kept confidential (private) unless disclosure is legally required. This will help the company and the FDA evaluate the pregnancy prevention program to prevent birth defects.
INITIAL: __________
PATIENT AGREEMENT/INFORMED CONSENT FOR FEMALE PATIENTS

I have received a copy of the Do Your P.A.R.T.™ brochure. My prescriber has answered all my questions about SORIATANE. I understand that it is my responsibility to follow my doctor’s instructions, and not to get pregnant during treatment with SORIATANE or for at least 3 years after I stop taking SORIATANE.

I now authorize my prescriber, ________________________________, to begin my treatment with SORIATANE.

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 childbearing potential. I have asked the patient if she has any questions regarding her treatment with SORIATANE and have answered those questions to the best of my ability.

Prescriber signature: ________________________________ Date: ________________

[Patient Copy]

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PATIENT AGREEMENT/INFORMED CONSENT
FOR FEMALE PATIENTS
To be completed by the patient* and signed by her prescriber

*Must also be initialed by the parent or guardian of a minor patient (under age 18)

Read each item below and initial in the space provided to show that you understand each item. Do not sign this consent and do not take SORIATANE® (acitretin) if there is anything that you do not understand.

(Patient’s name)

1. I understand that there is a very high risk that my unborn baby could have severe birth defects if I am pregnant or become pregnant while taking SORIATANE in any amount even for short periods of time. Birth defects have also happened in babies of women who became pregnant after stopping treatment with SORIATANE.
INITIAL: ____________

2. I understand that I must not become pregnant while taking SORIATANE and for at least 3 years after the end of my treatment with SORIATANE.
INITIAL: ____________

3. I know that I must avoid all alcohol, including drinks, food, medicines, and over-the-counter products that contain alcohol. I understand that the risk of birth defects may last longer than 3 years if I swallow any form of alcohol during therapy with SORIATANE, and for 2 months after I stop taking SORIATANE.
INITIAL: ____________

4. I understand that I must not have sexual intercourse, or I must use 2 separate, effective forms of birth control at the same time. The only exceptions are if I have had surgery to remove the womb (a hysterectomy) or my prescriber has told me I have gone completely through menopause.
INITIAL: ____________

5. I understand that I have to use 2 effective forms of birth control (contraception) at the same time for at least 1 month before starting SORIATANE, for the entire time of therapy with SORIATANE, and for at least 3 years after stopping SORIATANE.
INITIAL: ____________

6. I understand that any form of birth control can fail. Therefore, I must use 2 different methods at the same time, every time I have sexual intercourse.
INITIAL: ____________

7. I understand that the following are considered effective forms of birth control: Primary: Tubal ligation (having my tubes tied), partner’s vasectomy, birth control pills (not progestin-only “minipills”), injectable/implantable/insertable/topical (patch) hormonal birth control products, and IUDs (intrauterine devices). Secondary: Condoms (with or without spermicide, which is a special cream or jelly that kills sperm), diaphragms and cervical caps (which must be used with a spermicide), and vaginal sponges (contain spermicide). I understand that at least 1 of my 2 methods of birth control must be a primary method.
INITIAL: ____________

8. I will talk with my prescriber about any medicines or dietary supplements I plan to take while taking SORIATANE because certain birth control methods may not work if I am taking certain medicines or herbal products (for example, St. John’s wort).
INITIAL: ____________

9. Unless I have had a hysterectomy or my prescriber says I have gone completely through menopause, I understand that I must have 2 negative pregnancy test results before I can get a prescription to start SORIATANE. I understand that if the second pregnancy test is negative, I must start taking my SORIATANE within 7 days of specimen collection. I will then have pregnancy tests on a monthly basis during therapy with SORIATANE as instructed by my prescriber. In addition, for at least 3 years after I stop taking SORIATANE, I will have a pregnancy test every 3 months.
INITIAL: ____________

10. I understand that I should not start taking SORIATANE until I am sure that I am not pregnant and have negative results from 2 pregnancy tests.
INITIAL: ____________

11. I have received information on emergency contraception (birth control), including information on its availability over-the-counter.
INITIAL: ____________

12. I understand that my prescriber can give me a referral for a free contraception (birth control) counseling session and pregnancy testing.
INITIAL: ____________

13. I understand that on a monthly basis during therapy with SORIATANE and every 3 months for at least 3 years after stopping SORIATANE that I should receive counseling from my prescriber about contraception (birth control) and behaviors associated with an increased risk of pregnancy.
INITIAL: ____________

14. I understand that I must stop taking SORIATANE right away and call my prescriber if I get pregnant, miss my menstrual period, stop using birth control, or have sexual intercourse without using my 2 birth control methods during and at least 3 years after stopping SORIATANE.
INITIAL: ____________

15. If I do become pregnant while on SORIATANE or at any time within 3 years of stopping SORIATANE, I understand that I should report my pregnancy to Stiefel at 1-888-784-3335 (1-888-STIEFEL) or to the Food and Drug Administration (FDA) MedWatch program at 1-800-FDA-1088. The information I share will be kept confidential (private) unless disclosure is legally required. This will help the company and the FDA evaluate the pregnancy prevention program to prevent birth defects.
INITIAL: ____________
PATIENT AGREEMENT/INFORMED CONSENT FOR FEMALE PATIENTS

I have received a copy of the Do Your P.A.R.T.™ brochure. My prescriber has answered all my questions about SORIATANE. I understand that it is my responsibility to follow my doctor’s instructions, and not to get pregnant during treatment with SORIATANE or for at least 3 years after I stop taking SORIATANE.

I now authorize my prescriber, ________________________________, to begin my treatment with SORIATANE.

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 childbearing potential. I have asked the patient if she has any questions regarding her treatment with SORIATANE and have answered those questions to the best of my ability.

Prescriber signature: ________________________________ Date: ________________

[Prescriber Copy]

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CONTRACEPTION COUNSELING REFERRAL PROGRAM

Expert Counseling With No Added Expenses

Before you can start taking SORIATANE® (acitretin), you have to be sure that you are not pregnant and that you understand how to avoid pregnancy. That’s why Stiefel Laboratories, Inc. will pay for you to go to a contraception counselor. This specialist will provide you with expert counseling about birth control (contraception and avoiding pregnancy). This counseling is very important, even if you already feel you know about birth control, and even if you are not having sex or do not plan to have sex.

6 Simple Instructions

1. Make an appointment to see a contraception counselor and give him/her the attached forms. The counselor should call your prescriber if there are any questions about why you are there or about how the program works.

2. Notify your prescriber after you have had contraception counseling.

3. Ask the contraception counselor to mail a copy of the form to your prescriber. You will not get your first prescription for SORIATANE until your prescriber has received this signed form, and you must have negative results from 2 pregnancy tests. Your first test will be done at the time you and your prescriber decide if SORIATANE might be right for you. The second pregnancy test will usually be done during the first 5 days of your menstrual period right before you plan to start SORIATANE. If the second pregnancy test is negative, initiation of treatment with SORIATANE should begin within 7 days of the specimen collection. SORIATANE should be limited to a monthly supply.

4. You must use 2 effective forms of birth control (contraception) at the same time for at least 1 month before beginning treatment with SORIATANE, during treatment with SORIATANE, and for at least 3 years after you stop taking SORIATANE.

5. You are not required to pay any charges for the counseling by the contraception counselor. If you are asked to pay, have your contraception counselor send your signed Authorization for Use or Disclosure of Health Information form to the address below. The counselor should follow the instructions on the attached forms. The fee will be paid by Stiefel Laboratories, Inc.

6. Finally, if your contraception counselor performs a pregnancy test, the laboratory bill should be sent to the following address:

SORIATANE® Do Your P.A.R.T.™
5150 McCrimmon Parkway
Morrisville, NC 27560

Patient Copy

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CONTRACEPTION COUNSELING REFERRAL FORM (SORIATANE®)

Notes to Contraception Counselor

This patient, ______________________________________, is being considered for treatment with SORIATANE® (acitretin). She has been referred to you for contraception counseling before she receives a prescription for SORIATANE.

SORIATANE is a potent teratogen; therefore, it is essential to rule out pregnancy before her treatment begins and for you to fully inform the patient about effective contraception. The typical course of therapy with SORIATANE may last several months, depending upon the patient’s response to the medication. The patient must choose 2 effective forms of contraception to be used simultaneously for at least 1 month prior to initiation of therapy with SORIATANE, during therapy with SORIATANE, and for at least 3 years after discontinuing therapy with SORIATANE. According to the package insert for SORIATANE, the following are considered effective forms of contraception:

Primary: Tubal ligation, partner’s vasectomy, intrauterine devices, injectable/implantable/insertable hormonal birth control products, and birth control patch. Birth control pills that contain both estrogen and progestin (combination oral contraceptives) are considered an effective form of birth control; however, progestin-only (‘‘minipills’’) birth control pills should be avoided.

Secondary: Condoms (with or without spermicide), diaphragms and cervical caps (which must be used with a spermicide), and vaginal sponges (contain spermicide).

The patient must choose at least 1 primary form of contraception.

Please explain the patient’s options for contraception, the risk of possible contraceptive failure, and the requirements for achieving maximal effectiveness with her chosen methods. Please inform me if the patient does not choose 2 effective forms of contraception. The patient should also be counseled about emergency contraception.

Therapy cannot begin until pregnancy has been ruled out by negative results from 2 pregnancy tests with a sensitivity of at least 25 mIU per mL. The first test should be done at the time the patient decides to pursue therapy. The second test should be done during the first 5 days of the menstrual period immediately preceding the beginning of therapy with SORIATANE; or, if the patient has amenorrhea, the pregnancy test should be done at least 11 days after the last act of unprotected sexual intercourse (without using 2 effective forms of contraception simultaneously). If the second pregnancy test is negative, initiation of treatment with SORIATANE should begin within 7 days of the specimen collection. SORIATANE should be limited to a monthly supply.

Prescriber’s name: ___________________________________________________________________

Address: __________________________________________ Telephone: ____________________________

Prescriber’s signature: ____________________________________ Date: _____________

Information to Be Returned to Prescriber

I have provided the following for your patient ________________________________

☐ Comprehensive contraception counseling
☐ Information about emergency contraception
☐ The patient had a negative pregnancy test on ________________________________

The patient has chosen 2 methods of contraception.

☐ Yes ☐ No

Primary method: __________________________________ Secondary method: ________________________________

Name: ___________________________________ (Please affix label, or type or print clearly.)

Address: __________________________________ Telephone: ____________________________

Contraception counselor’s signature: ________________________________ Date: ____________

Prescriber Copy

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CONTRACEPTION COUNSELING REFERRAL FORM (SORIATANE®)

Reimbursement

NOTE: Reimbursement is offered only for contraception counseling and pregnancy testing, if performed. Other services that may be provided during this visit are not eligible for reimbursement.

The prescriber who actually prescribes SORIATANE® (acitretin) is not eligible for reimbursement by Stiefel®.

REIMBURSEMENT INSTRUCTIONS

To receive reimbursement, you must call a toll-free number for reimbursement. After you have provided all the requested information, a check will be sent to you by first-class mail.

Steps: Dial 1-888-784-3335 (1-888-STIEFEL).
  • You will be asked to provide the following information:
    - Your name and address
    - Your office phone number
    - Name of graduate school from which you graduated
    - Year of graduation
    - The name and address of the referring prescriber
    - The patient’s name
    - Whether you have provided contraception counseling and information on emergency contraception
    - Your normal and customary charge for providing these services
  • A check will then be processed and mailed to you within 10 days.
  • To check on the status of a previous request, you will need to provide only your name, address, and phone number. A representative will contact you to update your request status.

REIMBURSEMENT FOR PREGNANCY TEST

If you have performed pregnancy testing in the office or sent the patient directly to the laboratory, please instruct the laboratory to send the bill to the following address:

SORIATANE® Do Your P.A.R.T.™
5150 McCrimmon Parkway
Morrisville, NC 27560

Important: Your name and address must be included on the invoice from the laboratory.

The laboratory will be reimbursed directly.

NOTE TO CONSULTANTS: By participating in this program, you agree to provide Stiefel with access to additional information should it become necessary to confirm the appropriateness of this request for reimbursement. Stiefel reserves the right to place limitations on reimbursements or deny reimbursements in certain situations.
CONTRACEPTION COUNSELING REFERRAL FORM (SORIATANE®)

Notes to Contraception Counselor

This patient, ____________________, is being considered for treatment with SORIATANE® (acitretin). She has been referred to you for contraception counseling before she receives a prescription for SORIATANE.

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Secondary: Condoms (with or without spermicide), diaphragms and cervical caps (which must be used with a spermicide), and vaginal sponges (contain spermicide).

The patient must choose at least 1 primary form of contraception.

Please explain the patient’s options for contraception, the risk of possible contraceptive failure, and the requirements for achieving maximal effectiveness with her chosen methods. Please inform me if the patient does not choose 2 effective forms of contraception. The patient should also be counseled about emergency contraception.

Therapy cannot begin until pregnancy has been ruled out by negative results from 2 pregnancy tests with a sensitivity of at least 25 mIU per mL. The first test should be done at the time the patient decides to pursue therapy. The second test should be done during the first 5 days of the menstrual period immediately preceding the beginning of therapy with SORIATANE; or, if the patient has amenorrhea, the pregnancy test should be done at least 11 days after the last act of unprotected sexual intercourse (without using 2 effective forms of contraception simultaneously). If the second pregnancy test is negative, initiation of treatment with SORIATANE should begin within 7 days of the specimen collection. SORIATANE should be limited to a monthly supply.

Prescriber’s name: ___________________________________________________________________

(Please affix label, or type or print clearly.)

Address: ____________________________________________________ Telephone: ________________

Prescriber’s signature: ________________________________________ Date: _____________

Information to Be Returned to Prescriber

I have provided the following for your patient

☐ Comprehensive contraception counseling
☐ Information about emergency contraception
☐ The patient had a negative pregnancy test on ________________________

(Date)

The patient has chosen 2 methods of contraception.

☐ Yes ☐ No

Primary method: ______________________________ Secondary method: ____________________________________

Name: ____________________________________________ (Please affix label, or type or print clearly.)

Address: __________________________________________ Telephone: ____________________________

Contraception counselor’s signature: ________________________ Date: __________

Contraception Counselor Copy
CONTRACEPTION COUNSELING REFERRAL FORM (SORIATANE®)

Reimbursement

NOTE: Reimbursement is offered only for contraception counseling and pregnancy testing, if performed. Other services that may be provided during this visit are not eligible for reimbursement.

The prescriber who actually prescribes SORIATANE® (acitretin) is not eligible for reimbursement by Stiefel®.

REIMBURSEMENT INSTRUCTIONS

To receive reimbursement, you must call a toll-free number for reimbursement. After you have provided all the requested information, a check will be sent to you by first-class mail.

Steps: Dial 1-888-784-3335 (1-888-STIEFEL).
- You will be asked to provide the following information:
  - Your name and address
  - Your office phone number
  - Name of graduate school from which you graduated
  - Year of graduation
  - The name and address of the referring prescriber
  - The patient’s name
  - Whether you have provided contraception counseling and information on emergency contraception
  - Your normal and customary charge for providing these services
- A check will then be processed and mailed to you within 10 days.
- To check on the status of a previous request, you will need to provide only your name, address, and phone number. A representative will contact you to update your request status.

REIMBURSEMENT FOR PREGNANCY TEST

If you have performed pregnancy testing in the office or sent the patient directly to the laboratory, please instruct the laboratory to send the bill to the following address:

SORIATANE® Do Your P.A.R.T.™
5150 McCrimmon Parkway
Morrisville, NC 27560

Important: Your name and address must be included on the invoice from the laboratory.

The laboratory will be reimbursed directly.

NOTE TO CONSULTANTS: By participating in this program, you agree to provide Stiefel with access to additional information should it become necessary to confirm the appropriateness of this request for reimbursement. Stiefel reserves the right to place limitations on reimbursements or deny reimbursements in certain situations.

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CONTRACEPTION COUNSELING REFERRAL FORM (SORIATANE®)

Notes to Contraception Counselor

This patient, ____________________, is being considered for treatment with SORIATANE® (acitretin). She has been referred to you for contraception counseling before she receives a prescription for SORIATANE.

SORIATANE is a potent teratogen; therefore, it is essential to rule out pregnancy before her treatment begins and for you to fully inform the patient about effective contraception. The typical course of therapy with SORIATANE may last several months, depending upon the patient’s response to the medication. The patient must choose 2 effective forms of contraception to be used simultaneously for at least 1 month prior to initiation of therapy with SORIATANE, during therapy with SORIATANE, and for at least 3 years after discontinuing therapy with SORIATANE. According to the package insert for SORIATANE, the following are considered effective forms of contraception:

Primary: Tubal ligation, partner’s vasectomy, intrauterine devices, injectable/implantable/insertable hormonal birth control products, and birth control patch. Birth control pills that contain both estrogen and progestin (combination oral contraceptives) are considered an effective form of birth control; however, progestin-only (“minipills”) birth control pills should be avoided.

Secondary: Condoms (with or without spermicide), diaphragms and cervical caps (which must be used with a spermicide), and vaginal sponges (contain spermicide).

The patient must choose at least 1 primary form of contraception.

Please explain the patient’s options for contraception, the risk of possible contraceptive failure, and the requirements for achieving maximal effectiveness with her chosen methods. Please inform me if the patient does not choose 2 effective forms of contraception. The patient should also be counseled about emergency contraception.

Therapy cannot begin until pregnancy has been ruled out by negative results from 2 pregnancy tests with a sensitivity of at least 25 mIU per mL. The first test should be done at the time the patient decides to pursue therapy. The second test should be done during the first 5 days of the menstrual period immediately preceding the beginning of therapy with SORIATANE; or, if the patient has amenorrhea, the pregnancy test should be done at least 11 days after the last act of unprotected sexual intercourse (without using 2 effective forms of contraception simultaneously). If the second pregnancy test is negative, initiation of treatment with SORIATANE should begin within 7 days of the specimen collection. SORIATANE should be limited to a monthly supply.

Prescriber’s name: ___________________________________________________________________
(Address: __________________________________________ Telephone: ________________)
Prescriber’s signature: __________________________________ Date: _____________

Information to Be Returned to Prescriber

I have provided the following for your patient __________________________
(Name)

☐ Comprehensive contraception counseling
☐ Information about emergency contraception
☐ The patient had a negative pregnancy test on __________________________
(Date)

The patient has chosen 2 methods of contraception.
☐ Yes  ☐ No

Primary method: ____________________________________ Secondary method: ____________________________________

Name: __________________________________ Telephone: __________________________
(Address: __________________________________)

Contraception counselor’s signature: __________________________ Date: _____________

Return This Copy to Prescriber

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CONTRACEPTION COUNSELING REFERRAL FORM (SORIATANE®)

Reimbursement

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- You will be asked to provide the following information:
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  - Your office phone number
  - Name of graduate school from which you graduated
  - Year of graduation
  - The name and address of the referring prescriber
  - The patient’s name
  - Whether you have provided contraception counseling and information on emergency contraception
  - Your normal and customary charge for providing these services

- A check will then be processed and mailed to you within 10 days.
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Morrisville, NC 27560

Important: Your name and address must be included on the invoice from the laboratory.

The laboratory will be reimbursed directly.

NOTE TO CONSULTANTS: By participating in this program, you agree to provide Stiefel with access to additional information should it become necessary to confirm the appropriateness of this request for reimbursement. Stiefel reserves the right to place limitations on reimbursements or deny reimbursements in certain situations.

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AUTHORIZATION FOR USE OR DISCLOSURE OF HEALTH INFORMATION

I authorize the use or disclosure of health information about me as described below.

1. I agree to permit my doctor and Stiefel Laboratories, Inc., its affiliates, and those working with Stiefel Laboratories or its affiliates (Stiefel) to use and disclose health information about me.

2. I agree to permit Stiefel to receive the following health information about me: All health information related to reimbursement of certain costs related to lab work and physician counseling, and health information in my medical records that is relevant to my treatment with SORIATANE® (acitretin).

3. Stiefel is authorized to use the information to determine if I qualify for reimbursement under the Do Your P.A.R.T.™ program and, if it is determined that I qualify, in providing my doctor reimbursement for certain approved costs.

4. I understand that Stiefel is not a health care provider or health plan covered by federal privacy regulations, and when the information described above is disclosed to Stiefel it will no longer be protected by these regulations.

5. I understand that I may refuse to sign this authorization. If I do not sign, however, I understand that I will not be able to apply for or receive reimbursement of certain costs under the Do Your P.A.R.T.™ program.

6. I understand that I may revoke this authorization at any time by sending a written request to SORIATANE® Do Your P.A.R.T.™, 5150 McCrimmon Parkway, Morrisville, NC 27560, except to the extent that action has been taken in reliance on this authorization.

7. This authorization expires 1 year after my participation in the Do Your P.A.R.T.™ program ends.

____________________________________   ________________
Signature of patient or representative     Date

____________________________________
Patient name

____________________________________  ________________________
Name of personal representative (if applicable)  Relationship to patient

(A copy of this signed form will be provided to the patient.)

Patient Copy

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AUTHORIZATION FOR USE OR DISCLOSURE OF HEALTH INFORMATION

I authorize the use or disclosure of health information about me as described below.

1. I agree to permit my doctor and Stiefel Laboratories, Inc., its affiliates, and those working with Stiefel Laboratories or its affiliates (Stiefel) to use and disclose health information about me.

2. I agree to permit Stiefel to receive the following health information about me: All health information related to reimbursement of certain costs related to lab work and physician counseling, and health information in my medical records that is relevant to my treatment with SORIATANE® (acitretin).

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6. I understand that I may revoke this authorization at any time by sending a written request to SORIATANE®, Do Your P.A.R.T.™, 5150 McCrimmon Parkway, Morrisville, NC 27560, except to the extent that action has been taken in reliance on this authorization.

7. This authorization expires 1 year after my participation in the Do Your P.A.R.T.™ program ends.

____________________________________   ________________
Signature of patient or representative     Date

____________________________________
Patient name

____________________________________  ________________________
Name of personal representative (if applicable)  Relationship to patient

(A copy of this signed form will be provided to the patient.)

Stiefel Copy

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SORIATANE® DO YOUR P.A.R.T.™ ENROLLMENT PATIENT SURVEY

Please complete the following:

Last Name
First Name
Zip code (of your home address)

DIRECTIONS: Please read the questions carefully. It is possible that you will have to skip some questions. That’s okay. Not all questions will need to be answered. Some questions are specific to your current status for your therapy with SORIATANE (e.g., patients just starting therapy with SORIATANE, patients on active therapy, or patients who have either temporarily or permanently stopped therapy). The survey will instruct you on which questions to answer.

1. What is today’s date? Please enter: [GO TO Next Question]
   [ ]/ [ ]/ [ ]
   (Month) (Day) (Year)

2. Did you receive a Medication Guide explaining the safe use of and risks associated with SORIATANE? (Choose only one)
   □ Yes, from my doctor’s office
   □ Yes, from my pharmacy
   □ Yes, from both my doctor’s office and my pharmacy
   □ No
   □ I don’t know / I don’t remember

3. Did your doctor review the risks and benefits associated with SORIATANE with you? (Choose only one)
   □ Yes
   □ No, but someone else from my doctor’s office did
   □ No, no one discussed this with me
   □ I don’t know / I don’t remember

4. Did your doctor answer all of your questions about SORIATANE? (Choose only one)
   □ Yes
   □ No, but someone else from my doctor’s office did
   □ No, no one answered my questions
   □ I don’t know / I don’t remember

5. Did you complete and sign the Patient Agreement/Informed Consent for Female Patients form in the doctor’s office? (Choose only one)
   □ Yes
   □ No
   □ I don’t know / I don’t remember
6. Did you receive and read the contraception counseling referral form? (Choose only one)
   □ Yes, I received and read it
   □ Yes, I received but have not yet read it
   □ No
   □ I don’t know / I don’t remember

7. Are you currently taking SORIATANE®? (Choose only one)
   □ No [SKIP TO Question # 9]
   □ Yes [GO TO Next Question]

8. When did you start your current therapy with SORIATANE? (Enter approximate month and year)
   □ □ / □□□□ [SKIP TO Question # 12]
   (Month) (Year)

9. Read the responses below and choose the best answer: (Choose only one)
   □ I have not yet started therapy with SORIATANE [GO TO Question # 10]
   □ I have stopped taking SORIATANE [SKIP TO Question # 11]

10. When do you plan to BEGIN taking SORIATANE? (Enter the approximate month and year)
    □ □ / □□□□ [SKIP TO Question # 13]
        (Month) (Year)

11. What date did you STOP taking SORIATANE? (Enter the approximate month and year)
    □ □ / □□□□ [GO TO Next Question]
        (Month) (Year)

12. Were you pregnant when you BEGAN taking SORIATANE? (Choose only one)
    □ No
    □ Yes
    □ Don’t know

13. Did you have two negative pregnancy tests before receiving your first prescription for SORIATANE? (Choose only one)
    □ No [GO TO Next Question]
    □ Yes [GO TO Next Question]
    □ I don’t know [GO TO Next Question]
    □ I have not received my first prescription yet [SKIP TO Question # 20]

14. Where do you obtain your SORIATANE? (Check all that apply)
    □ Pharmacy
    □ Internet
    □ Other (specify): ______________________________
15. Removing the womb (uterus) is sometimes medically necessary, and is called a hysterectomy. Since you have been on SORIATANE have you had a hysterectomy? (Choose only one)

☐ No
☐ I don’t know
☐ Yes (If Yes, enter the approximate month and year below)

/  
(Month)  (Year)

16. Since you have been on SORIATANE, have you had both ovaries surgically removed? (Choose only one)

☐ No
☐ I don’t know
☐ Yes (If Yes, enter the approximate month and year below)

/  
(Month)  (Year)

17. Since you have been on SORIATANE, has your doctor told you that your ovaries stopped working and that you are in menopause? (Choose only one)

☐ No
☐ I don’t know
☐ Yes (If Yes, enter the approximate month and year below)

/  
(Month)  (Year)

18. Have you become pregnant since obtaining/taking your SORIATANE? (Choose only one)

☐ No
☐ I don’t know
☐ Yes (If Yes, enter the approximate month and year of the most recent pregnancy below)

/  
(Month)  (Year)

19. Since beginning treatment with SORIATANE, how often would you say that you used two effective and different forms of birth control (as described in the Do Your P.A.R.T.™ program) for each episode of sexual intercourse?

☐ Never
☐ Not very often
☐ Sometimes
☐ Often
☐ Always
20. Are you currently using 2 effective and different forms of birth control at each episode of sexual intercourse?
   ☐ Yes
   ☐ No
   ☐ I don’t know

   If Yes, please identify forms of birth control currently used (Check all that apply):
   ☐ Birth control patch
   ☐ Birth control pills (contains estrogen and progesterone)
   ☐ Birth control progestin-only mini-pill
   ☐ Injected hormonal birth control
   ☐ Inserted hormonal birth control
   ☐ Implanted hormonal birth control
   ☐ Intrauterine Device (IUD)
   ☐ Abstinence
   ☐ Withdrawal
   ☐ None
   ☐ Other
   (specify): ____________________________

21. How often are you given a pregnancy test? (Choose only one)
   ☐ Once a month
   ☐ Every other month
   ☐ Once every three months
   ☐ Once every six months
   ☐ Once a year
   ☐ Never
   ☐ Don’t know

22. To the best of your knowledge, enter the approximate month and year of your last pregnancy test that was performed.
   ☐ ☐ / ☐ ☐
   (Month) (Year)
   ☐ Check here if you can’t remember

23. Are you pregnant now? (Choose only one)
   ☐ No
   ☐ Yes
   ☐ Don’t know
INSTRUCTIONS: In this section, there are four statements that could be either True or False. Test your knowledge by reading each statement and determine if it is True or False. Choose only one answer for each statement.

24. Because of the risk of birth defects from SORIATANE, you need to start using two forms of birth control at least 1 month before you begin taking SORIATANE, for your entire treatment with SORIATANE, and for 3 years after you stop taking SORIATANE.
   - False
   - True

25. Alcohol (even small amounts contained in medicines or used in cooking) can increase the length of time SORIATANE is stored in a woman’s body, causing the risk of birth defects as long as 3 years after stopping SORIATANE.
   - False
   - True

26. Because of the risk of birth defects, it is important that women of reproductive potential do not drink alcohol during treatment with SORIATANE, and for two months after they stop treatment.
   - False
   - True

27. No person (male or female) should donate blood while taking SORIATANE and for at least 3 years after stopping therapy.
   - False
   - True

28. How would you like to complete future surveys? (Choose only one)
   - Paper form (mailed)
   - Internet (web-based)

END OF SURVEY – THANK YOU!

Please return the survey to:
SORIATANE® Do Your P.A.R.T.™ Survey
5150 McCrimmon Parkway
Morrisville, NC 27560

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SORIATANE® (ACITRETIN) DO YOUR P.A.R.T.™ PATIENT SURVEY REGISTRATION

Purpose of the Survey
The SORIATANE® Do Your P.A.R.T.™ (Pregnancy Prevention Actively Required During and After Treatment) patient survey is a short, easy-to-answer questionnaire that gathers information about how women who can get pregnant use SORIATANE, the importance of pregnancy prevention and patient understanding of the risks associated with using SORIATANE.

What to Expect
You will be asked to complete a survey when you register, every three months while you are taking SORIATANE and then twice a year for three years after you stop taking SORIATANE. We will remind you when a survey is ready for you to complete. Each survey will take only a few minutes of your time. You will complete your first survey on paper, but have your choice of completing future surveys on paper or via the Internet. If you choose “Internet” below and provide your e-mail address, you will be sent an e-mail with instructions on how to complete future surveys online.

Your Privacy
Your participation in the survey and any answers that you provide are completely confidential. Only the researchers and those working with the researchers managing the survey will know your identity. Your name and contact information will not be shared with others, and the answers you provide will never be identified with you in any presentation of the survey results.

Payment
We appreciate your participation in the SORIATANE Do Your P.A.R.T.™ patient survey. To compensate you for your time, we will send you a $50 American Express gift card for every survey you complete. The gift card can be used for purchases wherever American Express is accepted.

How to Register
Registration is simple. Just fill out the form below, and be sure to sign and date it. Then, place it in the provided postage-paid envelope along with your completed survey and drop it in the mail. Be sure to let us know how you would like to receive future surveys.

Participant Information (please print)
I agree to participate in the SORIATANE Do Your P.A.R.T.™ patient survey

Name: Last______________________ First____________________________ Middle Initial ____
Address: Street __________________ Apt #___ City ______________ State___ Zip Code_______
Telephone: ___________________ Best time to call: ____ am/pm

Doctor’s Name: ____________________________
Doctor’s Address: Street __________________ City ______________ State___ Zip Code_______

Most recent date that you began treatment with SORIATANE  Month ___ Day ___ Year ___

Signature: _________________________________ Date: _____________

How would you like to complete future surveys?

[ ] Paper Form
[ ] Internet   Your E-mail Address ____________________________________

Misplaced your envelope? Send your form and your survey to: SORIATANE® Do Your P.A.R.T.™ Survey
5150 McCrimmon Parkway
Morrisville, NC 27560
877-351-5495