

## MEDICATION GUIDE FOR PATIENTS

### **SORIATANE®**

[sor-RYE-uh-tane]

(acitretin)

CAPSULES

Read this Medication Guide carefully before you start taking Soriatane and read it each time you get more Soriatane. There may be new information.

The first information in this Guide is about birth defects and how to avoid pregnancy. **After this section there is important safety information about possible effects for any patient taking Soriatane.** ALL patients should read this entire Medication Guide carefully.

This information does not take the place of talking with your prescriber about your medical condition or treatment.

#### **What is the most important information I should know about Soriatane?**

**Soriatane can cause severe birth defects.** If you are a female who can get pregnant, you should use Soriatane only if you are not pregnant now, can avoid becoming pregnant for at least 3 years, and other medicines do not work for your severe psoriasis or you cannot use other psoriasis medicines. Information about effects on unborn babies and about how to avoid pregnancy is found in the next section: “What are the important warnings and instructions for females taking Soriatane?”.



#### **What are the important warnings and instructions for females taking Soriatane?**

- **Before you receive your Soriatane prescription, you should have discussed and signed a Patient Information/Consent 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.**
- **You must not take Soriatane if you are pregnant or might become pregnant during treatment or at any time for at least 3 years after you stop treatment because Soriatane can cause severe birth defects.**
- **During Soriatane treatment and for 2 months after you stop Soriatane treatment, you must avoid drinks, foods, and all medicines that contain alcohol. This includes over-the-counter products that contain alcohol. Avoiding alcohol is very important, because alcohol changes Soriatane into a drug that may take longer than 3 years to leave your body. The chance of**

birth defects may last longer than 3 years if you swallow any form of alcohol during Soriatane therapy and for 2 months after you stop taking Soriatane.

- **You and your prescriber must be sure you are not pregnant before you start Soriatane therapy. You must have negative results from 2 pregnancy tests before you start Soriatane treatment.** A negative result shows you are not pregnant. Because it takes a few days after pregnancy begins for a test to show that you are pregnant, the first negative test may not ensure you are not pregnant. Do not start Soriatane until you have negative results from 2 pregnancy tests.
  - The **first pregnancy 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. Your prescriber may suggest another time.
- After you start Soriatane therapy, you must have a pregnancy test repeated each month that you are taking Soriatane. This is to be sure that you are not pregnant during treatment because Soriatane can cause birth defects.
- For at least 3 years after stopping Soriatane treatment, you must have a pregnancy test repeated every three months to make sure that you are not pregnant.
- **Discuss effective birth control (contraception) with your prescriber. You must use 2 effective forms of birth control (contraception) at the same time during all of the following:**
  - for at least 1 month before beginning Soriatane treatment
  - during treatment with Soriatane
  - for at least 3 years after stopping Soriatane treatment
- **If you are sexually active, you must use 2 effective forms of birth control (contraception) at the same time even if you think you cannot become pregnant, unless 1 of the following is true for you:**
  - You had your womb (uterus) removed during an operation (a hysterectomy).
  - Your prescriber said you have gone completely through menopause (the “change of life”).
- **You can get a free birth control counseling session and pregnancy testing from a prescriber or family planning expert. Your prescriber can give you a Soriatane Patient Referral Form for this free session.**
- **You must use 2 effective forms of birth control (contraception) at the same time while you are on Soriatane treatment. You must use birth control for at least 1 month before you start Soriatane, during treatment, and at least 3 years after you stop Soriatane treatment.**

The following are considered effective forms of birth control:

**Primary Forms:**

- having your tubes tied (tubal ligation)
- partner's vasectomy
- IUD (intrauterine device)
- birth control pills that contain both estrogen and progestin (combination oral contraceptives)
- hormonal birth control products that are injected, implanted, or inserted in your body
- birth control patch

**Secondary Forms (use with a Primary Form):**

- diaphragms with spermicide
- latex condoms (with or without spermicide)
- cervical caps with spermicide

*At least 1 of your 2 methods of birth control must be a primary form.*

- **If you have sex at any time without using 2 effective forms of birth control (contraception) at the same time, or if you get pregnant or miss your period, stop using Soriatane and call your prescriber right away.**
- **Consider “Emergency Contraception” (EC) if you have sex with a male without correctly using 2 effective forms of birth control (contraception) at the same time.** EC is also called “emergency birth control” or the “morning after” pill. Contact your prescriber **as soon as possible** if you have sex without using 2 effective forms of birth control (contraception) at the same time, because EC works best if it is used within 1 or 2 days after sex. EC is not a replacement for your usual 2 effective forms of birth control (contraception) because it is not as effective as regular birth control methods.  
You can get EC from private doctors or nurse practitioners, women’s health centers, or hospital emergency rooms. You can get the name and phone number of EC providers nearest you by calling the free Emergency Contraception Hotline at 1-888-NOT-2-LATE (1-888-668-2528).
- **Stop taking Soriatane right away and contact your prescriber if you get pregnant while taking Soriatane or at any time for at least 3 years after treatment has stopped. You need to discuss the possible effects on the unborn baby with your prescriber.**
- **If you do become pregnant while taking Soriatane or at any time for at least 3 years after stopping Soriatane, you should report your pregnancy to Stiefel Laboratories, Inc. at 1-888-784-3335 (STIEFEL) or directly to the Food and Drug Administration (FDA) MedWatch program (1-800-FDA-1088).** Your name will be kept in private (confidential). The information you share will help the FDA and the manufacturer evaluate the Pregnancy Prevention Program for Soriatane.
- **Do not take Soriatane if you are breast feeding.** Soriatane can pass into your milk and may harm your baby. You will need to choose either to breast feed or take Soriatane, but not both.

### **What should males know before taking Soriatane?**

Small amounts of Soriatane are found in the semen of males taking Soriatane. Based upon available information, it appears that these small amounts of Soriatane in semen pose little, if any, risk to an unborn child while a male patient is taking the drug or after it is discontinued. Discuss any concerns you have about this with your prescriber.

**All patients should read the rest of this Medication Guide.**

### **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 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 Soriatane's possible benefits outweigh its possible risks.

Soriatane may not work right away. You may have to wait 2 to 3 months before you get the full benefit of Soriatane. Psoriasis gets worse for some patients when they first start Soriatane treatment.

Soriatane has not been studied in children.

### **Who should not take Soriatane?**

- **Do NOT take Soriatane if you can get pregnant.** Do not take Soriatane if you are pregnant or might get pregnant during Soriatane treatment or at any time for **at least 3 years** after you stop Soriatane treatment (see "What are the important warnings and instructions for females taking Soriatane?").

- **Do NOT take Soriatane if you are breast feeding.** Soriatane can pass into your milk and may harm your baby. You will need to choose either to breast feed or take Soriatane, but not both.

- **Do NOT take Soriatane if you have severe liver or kidney disease.**

- **Do NOT take Soriatane if you have repeated high blood lipids** (fat in the blood).

- **Do NOT take Soriatane if you take these medicines:**

- methotrexate
- tetracyclines

The use of these medicines with Soriatane may cause serious side effects.

- **Do NOT take Soriatane if you are allergic to acitretin**, the active ingredient in Soriatane, to any of the other ingredients (see the end of this Medication Guide for a list of all the ingredients in Soriatane), or to any similar drugs (ask your prescriber or pharmacist whether any drugs you are allergic to are related to Soriatane).

**Tell your prescriber if you have or ever had:**

- diabetes or high blood sugar
- liver problems
- kidney problems
- high cholesterol or high triglycerides (fat in the blood)
- heart disease

- depression
- alcoholism
- an allergic reaction to a medication

Your prescriber needs this information to decide if Soriatane is right for you and to know what dose is best for you.

**Tell your prescriber about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines can cause serious side effects if taken while you also take Soriatane. Some medicines may affect how Soriatane works, or Soriatane may affect how your other medicines work. **Be especially sure to tell your prescriber if you are taking the following medicines:**

- methotrexate
- tetracyclines
- phenytoin
- vitamin A supplements
- progestin-only oral contraceptives (“minipills”)
- Tegison<sup>®</sup> or Tigason (etretinate). Tell your prescriber if you have ever taken this medicine in the past.
- St. John’s Wort herbal supplement

**Tell your prescriber if you are getting phototherapy treatment.** Your doses of phototherapy may need to be changed to prevent a burn.

#### **How should I take Soriatane?**

- Take Soriatane with food.
- Be sure to take your medicine as prescribed by your prescriber. The dose of Soriatane varies from patient to patient. The number of capsules you must take is chosen specially for you by your prescriber. This dose may change during treatment.
- If you miss a dose, do not double the next dose. Skip the missed dose and resume your normal schedule.
- If you take too much Soriatane (overdose), call your local poison control center or emergency room.

You should have blood tests for liver function, cholesterol and triglycerides before starting treatment and during treatment to check your body’s response to Soriatane. Your prescriber may also do other tests.

Once you stop taking Soriatane, your psoriasis may return. Do *not* treat this new psoriasis with leftover Soriatane. It is important to see your prescriber again for treatment recommendations because your situation may have changed.

#### **What should I avoid while taking Soriatane?**

- **Avoid pregnancy.** See “What is the most important information I should know about Soriatane?”, and “What are the important warnings and instructions for females taking Soriatane?”.
- **Avoid breast feeding.** See “What are the important warnings and instructions for females taking Soriatane?”.
- **Avoid alcohol.** Females must avoid drinks, foods, medicines, and over-the-counter products that contain alcohol. The risk of birth defects may continue

for longer than 3 years if you swallow any form of alcohol during Soriatane treatment and for 2 months after stopping Soriatane (see “What are the important warnings and instructions for females taking Soriatane?”).

- **Avoid giving blood. Do not donate blood** while you are taking Soriatane and **for at least 3 years after stopping** Soriatane treatment. Soriatane in your blood can harm an unborn baby if your blood is given to a pregnant woman. Soriatane does not affect your ability to receive a blood transfusion.
- **Avoid progestin-only birth control pills (“minipills”).** This type of birth control pill may not work while you take Soriatane. Ask your prescriber if you are not sure what type of pills you are using.
- **Avoid night driving if you develop any sudden vision problems.** Stop taking Soriatane and call your prescriber if this occurs (see “Serious side effects”).
- **Avoid non-medical ultraviolet (UV) light.** Soriatane can make your skin more sensitive to UV light. Do not use sunlamps, and avoid sunlight as much as possible. If you are taking light treatment (phototherapy), your prescriber may need to change your light dosages to avoid burns.
- **Avoid dietary supplements containing vitamin A.** Soriatane is related to vitamin A. Therefore, do not take supplements containing vitamin A, because they may add to the unwanted effects of Soriatane. Check with your prescriber or pharmacist if you have any questions about vitamin supplements.
- **DO NOT SHARE Soriatane with anyone else, even if they have the same symptoms.** Your medicine may harm them or their unborn child.

#### **What are the possible side effects of Soriatane?**

- **Soriatane can cause birth defects.** 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 Soriatane treatment. 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:

- **Bad headaches, nausea, vomiting, blurred vision.** These symptoms can be signs of increased brain pressure that can lead to blindness or even death.
- **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 Soriatane treatment stops. If you develop any vision problems or eye pain stop taking Soriatane and call your prescriber.
- **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. It is very important to stop taking Soriatane and call your prescriber right away if you develop such problems.

- **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.
- **Aches or pains in your bones, joints, muscles, or back; trouble moving; 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.

**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 Soriatane dose 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.
  - **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 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.

#### **How should I store Soriatane?**

Keep Soriatane away from sunlight, high temperature, and humidity. **Keep Soriatane away from children.**

#### **What are the ingredients in Soriatane?**

Active ingredient: acitretin

Inactive ingredients: microcrystalline cellulose, sodium ascorbate, gelatin, black monogramming ink and maltodextrin (a mixture of polysaccharides). Gelatin capsule shells contain gelatin, iron oxide (yellow, black, and red), and titanium dioxide. They may also contain benzyl alcohol, carboxymethylcellulose sodium, edetate calcium disodium.

**General information about the safe and effective use of Soriatane**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Soriatane for a condition for which it was not prescribed. Do not give Soriatane to other people, even if they have the same symptoms that you have.

This Medication Guide summarizes the most important information about Soriatane. If you would like more information, talk with your prescriber. You can ask your pharmacist or prescriber for information about Soriatane that is written for health professionals.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Do Your P.A.R.T. is a trademark and SORIATANE is a registered trademark of Stiefel Laboratories, Inc.

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Manufactured for



Stiefel Laboratories, Inc.  
Research Triangle Park, NC 27709

March 2011

SRN:1MG



**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<sup>®</sup> (acitretin).
3. Stiefel is authorized to use the information to determine if I qualify for reimbursement under the Do Your P.A.R.T.<sup>™</sup> 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 Stiefel Laboratories, Inc., Attn: 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)  
(A copy of this signed form will be provided to the patient.)

\_\_\_\_\_  
Relationship to patient

Patient Copy



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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.
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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** (birth control) to be used simultaneously for at least 1 month prior to initiation of SORIATANE therapy, during SORIATANE therapy, and for at least 3 years after discontinuing SORIATANE therapy. According to the SORIATANE package insert, 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 ("mini-pill") birth control pills should be avoided.

Secondary: Latex condoms (with or without spermicide), diaphragms and cervical caps (which must be used with a 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/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 SORIATANE therapy; 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).

SORIATANE prescriber's name: \_\_\_\_\_  
(Please affix label, or type or print clearly.)

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

SORIATANE prescriber's signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Information to Be Returned to SORIATANE 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: \_\_\_\_\_  
(Please affix label, or type or print clearly.)

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Contraception counselor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Contraception Counselor Copy



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## 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<sup>®</sup> (acitretin) is not eligible for reimbursement by Stiefel.**

### REIMBURSEMENT INSTRUCTIONS

To receive reimbursement, you must call a toll-free number and enter the designated branch 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 (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 SORIATANE 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:

Stiefel Laboratories, Inc.  
Attn: Director, Global Clinical Safety and Pharmacovigilance  
20 T.W. Alexander Drive  
Research Triangle Park, NC 27709

*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 PROGRAM

Expert Counseling With No Added Expenses



Before you can start taking SORIATANE<sup>®</sup> (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 SORIATANE prescriber if there are any questions about why you are there or about how the program works.

2

Notify your SORIATANE prescriber after you have had contraception counseling.

3

Ask the contraception counselor to mail a copy of the form to your SORIATANE 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, but your prescriber may suggest a different time.

4

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

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:

Stiefel Laboratories, Inc.  
Attn: Director, Global Clinical Safety and Pharmacovigilance  
20 T.W. Alexander Drive  
Research Triangle Park, NC 27709

Patient Copy



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Secondary: Latex condoms (with or without spermicide), diaphragms and cervical caps (which must be used with a 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/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 SORIATANE therapy; 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).

SORIATANE prescriber's name: \_\_\_\_\_  
(Please affix label, or type or print clearly.)

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

SORIATANE prescriber's signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Information to Be Returned to SORIATANE 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: \_\_\_\_\_  
(Please affix label, or type or print clearly.)

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Contraception counselor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

SORIATANE Prescriber Copy



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2011

## 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<sup>®</sup> (acitretin) is not eligible for reimbursement by Stiefel.**

### REIMBURSEMENT INSTRUCTIONS

To receive reimbursement, you must call a toll-free number and enter the designated branch 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 (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 SORIATANE 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:

Stiefel Laboratories, Inc.  
Attn: Director, Global Clinical Safety and Pharmacovigilance  
20 T.W. Alexander Drive  
Research Triangle Park, NC 27709

*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 SORIATANE therapy, during SORIATANE therapy, and for at least 3 years after discontinuing SORIATANE therapy. According to the SORIATANE package insert, 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 ("mini-pill") birth control pills should be avoided.

Secondary: Latex condoms (with or without spermicide), diaphragms and cervical caps (which must be used with a 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/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 SORIATANE therapy; 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).

SORIATANE prescriber's name: \_\_\_\_\_  
(Please affix label, or type or print clearly.)

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

SORIATANE prescriber's signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Information to Be Returned to SORIATANE 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: \_\_\_\_\_  
(Please affix label, or type or print clearly.)

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Contraception counselor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Return This Copy to SORIATANE Prescriber



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## 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 and enter the designated branch 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 (STIEFEL).

- You will hear recorded instructions on how to obtain reimbursement as a contraception counselor.
- 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 SORIATANE 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:

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Attn: Director, Global Clinical Safety and Pharmacovigilance  
20 T.W. Alexander Drive  
Research Triangle Park, NC 27709

*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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COVER

HEAD:

SERIOUS TREATMENT

SERIOUS DECISIONS

COPY:

**DO YOUR P.A.R.T.™**

Pregnancy Prevention **A**ctively **R**equired During & After **T**reatment

SIG:

CAUSES BIRTH  
DEFECTS



DO NOT GET  
PREGNANT

new Soriatane logo

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BOXED WARNING:

CAUSES BIRTH  
DEFECTS



DO NOT GET  
PREGNANT

CONTRAINDICATIONS AND WARNINGS: SORIATANE<sup>®</sup> (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 SORIATANE therapy. For patients with amenorrhea, the second test should be done at least 11 days after the last act of unprotected sexual intercourse. Timing of pregnancy testing throughout the treatment course should be monthly or individualized based on the prescriber's clinical judgment. Females must sign a Patient Information/Consent 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 product information. Females who have undergone treatment with Tegison<sup>®</sup> (etretinate) must continue to follow the contraception requirements for Tegison.

**FAIR BALANCE:**

Less frequent, but potentially serious, adverse events include hepatotoxicity, pancreatitis, and pseudotumor cerebri (please see Warnings in complete product information), as well as hyperostosis, alterations in lipids and possible cardiovascular effects, and ophthalmologic effects.

HEAD:  
**INTRODUCTION**

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**ABOUT SORIATANE**

SORIATANE<sup>®</sup> (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 Soriatane's possible benefits outweigh its possible risks.

In women of child bearing 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<sup>™</sup> PROGRAM**

This program applies to you because your doctor has prescribed SORIATANE for you. This program is for women of child bearing 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, SORIATANE use.



HEAD:

**GENERAL INFORMATION**

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**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 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 breast-feed
- 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
- Avoid nonmedical ultraviolet (UV) light
- Avoid dietary supplements containing vitamin A

## 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 Soriatane treatment. 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:

- **Bad headaches, nausea, vomiting, blurred vision.** These symptoms can be signs of increased brain pressure that can lead to blindness or even death.
- **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 Soriatane treatment stops. If you develop any vision problems or eye pain stop taking Soriatane and call your prescriber.
- **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. It is very important to stop taking Soriatane and call your prescriber right away if you develop such problems.
- **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.
- **Aches or pains in your bones, joints, muscles, or back; trouble moving; 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.

**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 Soriatane dose 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.
- **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 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.

COPY:

**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 (should have a pregnancy test each month before receiving 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
- 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 therapy.**
- 4. You MUST NOT donate blood during therapy and for 3 years after treatment discontinuation.**
- 5. You MUST sign the Informed Consent.**

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

SORIATANE SCHEDULE FOR PREGNANCY PREVENTION & SAFE PREGNANCY PLANNING					
	1 MONTH BEFORE TREATMENT	BEFORE TREATMENT	DURING SORIATANE TREATMENT	2 MONTHS AFTER TREATMENT	3 YEARS AFTER TREATMENT
2 FORMS OF BIRTH CONTROL	—————→				
2 NEGATIVE PREGNANCY TESTS		—————→			
ONGOING PREGNANCY TESTS	Each month before receiving prescription and every 3 months for 3 years after stopping treatment				
NO ALCOHOL			—————→		
NO BLOOD DONATION			—————→		

SIGN INFORMED CONSENT		→		
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HEAD:

**AVOIDING PREGNANCY**



COPY:

**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.)
- Use 2 forms of birth control at the same time, for at least one month before and during your SORIATANE treatment and for at least 3 years after you stop Soriatane treatment. 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 "mini-pills")
- 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
- Latex condom with or without spermicide

Before you receive your Soriatane prescription, you should have discussed and signed a Patient Information/Consent 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.

CALL-OUT:

## **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](http://www.arhp.org)**
- Planned Parenthood: **[www.plannedparenthood.org](http://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.otispregnancy.org](http://www.otispregnancy.org)**
- Centers for Disease Control and Prevention:  
**[www.cdc.gov](http://www.cdc.gov)**

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

### THIRD INSIDE SPREAD/RIGHT [PAGE 5]

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#### **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:

- Call your physician and the emergency contraception hotline **1-888-NOT-2-LATE (1-888-668-2528)** immediately

### **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 is commonly referred to as the “morning-after pill,” and needs to be used 1 to 2 days 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 (STIEFEL)**
- Or call FDA MedWatch at **1-800-FDA-1088 (1-800-332-1088)**

CALL-OUT:

### **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.

[FOURTH INSIDE SPREAD/LEFT \[PAGE 6\]](#)

### **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 breast-feeding?**

Do not take SORIATANE if you’re breast-feeding. 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.

## FOURTH INSIDE SPREADS/RIGHT [PAGE 7]

HEAD:

### **BIRTH CONTROL METHODS**

COPY:

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 box on page 4.

CALL-OUT:

#### **What about MINI-PILLS?**

Do not use “mini-pills,” 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 PILLS<sup>1</sup>**

“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 (“mini-pills”).

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

Advantages:

- Studied for many years; long-term safety is well understood
- Can make monthly periods lighter and lessen cramps
- Highly effective

Disadvantages:

- You have to remember to take a pill every day
- May cause mild side effects
- May not be for women with high blood pressure or who are over 35 and smoke

**Effectiveness:** fewer than 1 in 100 women will become pregnant in the first year with perfect use; with typical use, 8 in 100 women will become pregnant.

## FIFTH INSIDE SPREAD/LEFT [PAGE 8]

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### **BIRTH CONTROL PATCH<sup>2</sup>**

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. Each patch generally lasts a week, and most women wear no patch for 1 week per month.

Advantages:

- Simple to use
- Highly effective
- Can make monthly periods lighter

Disadvantages:

- May cause skin irritation
- May peel off
- Possible to forget to apply a new patch
- May be less effective in women weighing more than 198 pounds
- May cause mild side effects
- May not be for women with high blood pressure who are over 35 and smoke

**Effectiveness:** fewer than 1 in 100 women will become pregnant in the first year with perfect use; with typical use, 8 in 100 women will become pregnant.

### **INTRAUTERINE DEVICE<sup>3</sup>**

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 of an egg, possibly by affecting movement of sperm or egg.

Advantages:

- One of the most effective forms of birth control
- Can last up to 5-12 years
- Effective immediately

Disadvantages:

- Requires a medical procedure; insertion may cause discomfort or pain
- Periods may be heavier and longer for a few months or more
- May cause mild side effects

**Effectiveness:** Fewer than 1 in 100 women will become pregnant after having an IUD implanted, with perfect use; with typical use, 1 in 100 women will become pregnant.

## FIFTH INSIDE SPREAD/RIGHT [PAGE 9]

COPY:

## **INJECTED<sup>4</sup> OR INSERTED<sup>5,6</sup> HORMONAL BIRTH CONTROL**

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

**Injected hormones:** This form is given to you by your healthcare provider at specific time intervals (ranging between 4 and 12 weeks apart). These hormone shots prevent your ovaries from releasing eggs and may also keep sperm from joining with an egg.

Advantages:

- Highly effective
- Hard to forget

Disadvantages:

- Inconvenient and painful to get a regular shot at your doctor's office
- May cause mild side effects

**Effectiveness:** 3 in 1000 women will become pregnant in the first year of use.

**Inserted hormones:** This form is usually called the "vaginal contraceptive 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.

Advantages:

- No office procedure required
- One of the most effective forms of birth control

Disadvantages:

- May be inserted incorrectly, decreasing effectiveness
- May cause irritation or discharge
- Should not be used at the same time as a diaphragm

**Effectiveness:** fewer than 1 in 100 women will become pregnant in the first year with perfect use; with typical use, 8 out of every 100 women will become pregnant in the first year.

COPY:

### **TUBAL LIGATION<sup>7</sup> (“HAVING YOUR TUBES TIED”) OR YOUR PARTNER’S VASECTOMY<sup>8</sup>**

Sterilization of women and men require operations.

“Having your tubes tied” (or tubal ligation) is intended to block a woman’s fallopian tubes, where sperm would join with an egg.

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 time before all the live sperm are gone.

Advantages:

- Highly effective
- No medications to remember
- Permanent
- No effect on sexual pleasure

Disadvantages:

- Requires a more major operation for women, and a minor operation for men
- May only occasionally be reversed with additional surgery

**Tubal ligation effectiveness:** up to 1 in 100 women will become pregnant each year after having a tubal ligation.

**Vasectomy effectiveness:** up to 1 in 1000 men will become fertile again after a vasectomy has been performed.

### **CONTINUOUS ABSTINENCE<sup>9</sup>**

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

Advantages:

- 100% effective
- Prevents sexually transmitted infections
- No medical or hormonal side effects
- Endorsed by many religious groups

Disadvantages:

- People may find it difficult to abstain for long periods of time.
- Women and men often end their abstinence without being prepared to protect themselves against pregnancy or infection.
- Abstinence can only work when both partners agree to it.

## MEDICALLY CONFIRMED MENOPAUSE<sup>10</sup>

**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.

**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.

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.

## HYSTERECTOMY<sup>11</sup>

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.

## **SECONDARY METHODS**

You may choose 1 from these options to use with a primary method. Each of these methods (except condoms) must be used with spermicide. 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.

### **DIAPHRAGM<sup>6,12</sup>**

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. A diaphragm can be a good secondary way to prevent pregnancy.

The diaphragm must be used with spermicide, and can be inserted up to 6 hours before sex. If more than 6 hours pass, spermicide needs to be reapplied.

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

Advantages:

- Can be inserted quickly
- Works immediately
- Has no effect on a woman's natural hormones

Disadvantages:

- May be inserted incorrectly
- Must be removed within 24 hours
- Should not be used with a vaginal contraceptive ring
- Needs to be refitted after significant weight gain or loss
- May increase the risk of urinary tract infections

**Effectiveness:** 6 in 100 women will become pregnant in the first year with perfect use; with typical use, 16 in 100 women will become pregnant.

## SEVENTH INSIDE SPREAD/LEFT [PAGE 12]

COPY:

### **CERVICAL CAP<sup>12</sup>**

The cervical cap is very similar to the diaphragm, except that it is smaller and covers only the cervix. It is used with spermicide and it should not be left in longer than 48 hours. It is more complicated to insert correctly, but could be preferred by women who are prone to urinary tract infections.

Advantages:

- Works immediately
- Has no effect on a woman's natural hormones

Disadvantages:

- Is OFTEN inserted incorrectly
- Must be removed within 48 hours
- Should not be used with a vaginal contraceptive ring
- Needs to be refitted after significant weight gain or loss

**Effectiveness:** 9 in 100 women will become pregnant in the first year with perfect use; with typical use, 16 in 100 women will become pregnant.

### **CONDOM<sup>13</sup>**

This form of birth control traps the sperm, preventing it from entering your body. When applied and used properly, it can be a highly effective secondary way to prevent pregnancy.

Advantages:

- Available without a prescription
- Doesn't change anything in your body
- Latex condoms help protect against sexually transmitted disease

Disadvantages:

- May break
- Often used incorrectly
- A barrier between you and your partner

**Effectiveness:** fewer than 2 in 100 women will become pregnant in the first year with perfect use; with typical use, 15 in 100 will become pregnant.



HEAD:

**PATIENT SELF-EVALUATION**

COPY:

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. SORIATANE treatment 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.

HEAD:

**ANSWERS**

COPY:

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.

EIGHTH INSIDE SPREAD/RIGHT [PAGE 15]

**YOUR PERSONAL RECORD**

NAME: \_\_\_\_\_

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

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, right before you plan to start SORIATANE (but your doctor might suggest another time).

**2** START OF MENSTRUAL PERIOD \_\_\_\_\_

TEST DATE \_\_\_\_\_ TEST RESULT \_\_\_\_\_

DATE SORIATANE THERAPY BEGAN \_\_\_\_\_

**FOLLOW-UP APPOINTMENTS**

DATE \_\_\_\_\_ TIME \_\_\_\_\_

DATE \_\_\_\_\_ TIME \_\_\_\_\_

DATE \_\_\_\_\_ TIME \_\_\_\_\_

DATE \_\_\_\_\_ TIME \_\_\_\_\_

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DATE \_\_\_\_\_ TIME \_\_\_\_\_

DATE \_\_\_\_\_ TIME \_\_\_\_\_

DATE SORIATANE THERAPY STOPPED \_\_\_\_\_

**FOLLOW-UP APPOINTMENTS**

DATE \_\_\_\_\_ TIME \_\_\_\_\_

DATE \_\_\_\_\_ TIME \_\_\_\_\_

DATE \_\_\_\_\_ TIME \_\_\_\_\_

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DATE \_\_\_\_\_ TIME \_\_\_\_\_

NINTH INSIDE SPREAD/LEFT [PAGE 16]

**NOTES/PERSONAL CONTACT INFORMATION**

**PHYSICIAN NAME:**

**PHYSICIAN PHONE:**

**PHARMACY NAME:**

PHARMACY PHONE:

OTHER:

OTHER:

NINTH INSIDE SPREAD/RIGHT [POCKET]

HEAD:  
IMPORTANT PHONE NUMBERS

COPY:  
BIRTH CONTROL COUNSELING 1-800-739-6700

EMERGENCY CONTRACEPTION HOTLINE 1-888-NOT-2-LATE  
(1-888-668-2528)

IF YOU BECOME PREGNANT 1-888-784-3335 (STIEFEL)  
or  
1-800-FDA-1088 (1-800-332-1088)

BACK COVER  
updated Soriatane logo



CAUSES BIRTH  
DEFECTS



DO NOT GET  
PREGNANT

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April 2011

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- 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 Soriatane Patient Agreement/Informed Consent 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<sup>®</sup>? (Choose only one)

- No [SKIP TO Question # 9]
- Yes [GO TO Next Question]

8. When did you start your current Soriatane therapy? (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 Soriatane therapy [GO TO Question # 10]
- I have stopped Soriatane therapy [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 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):

- |   |   |
|---|---|
| <input type="checkbox"/> Birth control patch                                      | <input type="checkbox"/> Tubal ligation |
| <input type="checkbox"/> Birth control pills (contains estrogen and progesterone) | <input type="checkbox"/> Vasectomy      |
| <input type="checkbox"/> Birth control mini-pill                                  | <input type="checkbox"/> Condoms        |

- |   |   |
|---|---|
| <input type="checkbox"/> Injected hormonal birth control  | <input type="checkbox"/> Diaphragm                      |
| <input type="checkbox"/> Inserted hormonal birth control  | <input type="checkbox"/> Cervical Cap                   |
| <input type="checkbox"/> Implanted hormonal birth control | <input type="checkbox"/> Spermicide                     |
| <input type="checkbox"/> Intrauterine Device (IUD)        | <input type="checkbox"/> Natural family planning method |
| <input type="checkbox"/> Abstinence                       | <input type="checkbox"/> Emergency contraception        |
| <input type="checkbox"/> Withdrawal                       |   |
| <input type="checkbox"/> None                             |   |
| <input type="checkbox"/> 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 from cold remedies) 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 Soriatane treatment, 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<sup>®</sup> Do Your P.A.R.T.<sup>™</sup> Survey**

**2655 Meridian Parkway**

**Durham, NC 27713**

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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 SORIATANE treatment.

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 SORIATANE therapy, 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 SORIATANE therapy, and for at least 3 years after SORIATANE treatment has stopped.

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, injectable/implantable/insertable/topical (patch) hormonal birth control products, and IUDs (intrauterine devices). Secondary: Latex 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). 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 during my SORIATANE treatment because certain birth control methods may not work if I am taking certain medicines or herbal products (for example, Saint 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 will then have pregnancy tests on a monthly basis during my SORIATANE therapy as instructed by my prescriber. In addition, for at least 3 years after the end of my treatment with 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).

INITIAL: \_\_\_\_\_

**12.** I understand that my prescriber can give me a referral for a free contraceptive (birth control) counseling session and pregnancy testing.

INITIAL: \_\_\_\_\_

**13.** I understand that on a monthly basis during SORIATANE therapy and every 3 months for at least 3 years after stopping Soriatane treatment 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 treatment.

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 and its affiliates at 1-888-784-3335 (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: \_\_\_\_\_

**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 SORIATANE treatment 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 SORIATANE treatment.

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 SORIATANE therapy, 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 SORIATANE therapy, and for at least 3 years after SORIATANE treatment has stopped.

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, injectable/implantable/insertable/topical (patch) hormonal birth control products, and IUDs (intrauterine devices). Secondary: Latex 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). 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 during my SORIATANE treatment because certain birth control methods may not

work if I am taking certain medicines or herbal products (for example, Saint 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 will then have pregnancy tests on a monthly basis during my SORIATANE therapy as instructed by my prescriber. In addition, for at least 3 years after the end of my treatment with 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).  
INITIAL: \_\_\_\_\_

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

13. I understand that on a monthly basis during SORIATANE therapy and every 3 months for at least 3 years after stopping Soriatane treatment 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 treatment.  
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 and its affiliates at 1-888-784-3335 (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: \_\_\_\_\_

**I have received a copy of the Do Your P.A.R.T<sup>TM</sup> 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 SORIATANE treatment 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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## The SORIATANE Do Your P.A.R.T. Survey: Patient Brochure Copy

### Tri-Fold Brochure Panel Reference:

#### Printed Side: Front

<b>Panel 1: Inside Fold Panel</b>	<b>Panel 2: Back Panel</b>	<b>Panel 3: Front Panel</b>
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#### Printed Side: Back

<b>Panel 4: Inside Left Panel</b>	<b>Panel 5: Inside Center Panel</b>	<b>Panel 6: Inside Right Panel</b>
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#### Panel 1: Inside Fold Panel

[GRAPHIC: Woman of child bearing potential]

*What is the SORIATANE<sup>®</sup> (acitretin) **Do Your P.A.R.T.**<sup>™</sup> 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 SORIATANE use. 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.

**Panel 2: Back Panel**

For more information, visit the SORIATANE<sup>®</sup> (*acitretin*) **Do Your P.A.R.T.**<sup>™</sup> website at [www.soriatane.com](http://www.soriatane.com).

**HELPFUL PHONE NUMBERS:**

BIRTH CONTROL COUNSELING:	1-800-739-6700
EMERGENCY CONTRACEPTION HOTLINE:	1-888-NOT-2-LATE (1-888-668-2528)
IF YOU BECOME PREGNANT OR HAVE A SIDE EFFECT FROM TAKING SORIATANE:	1-888-784-3335 (1-888-STIEFEL) OR 1-800-FDA-1088 (1-800-332-1088)

[Soriatane Logo]



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**Panel 3: Front Panel**

[GRAPHIC: Photograph of woman of child bearing potential]

The SORIATANE<sup>®</sup> (*acitretin*) **Do Your P.A.R.T.**<sup>™</sup> Survey: A Patient's Guide to Participation  
**Pregnancy Prevention Actively Required During & After Treatment**

[GRAPHIC: Soriatane logo]

**Panel 4: Inside Left Panel**[Graphic: Woman of Child-bearing potential]*Why Should You Participate?*

Your doctor has asked you to participate in the SORIATANE<sup>®</sup> (*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.

[GRAPHIC: Survey timeline]

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

**Panel 5: Inside Center Panel**

[Graphic Woman of Child-Bearing Potential]  
*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<sup>®</sup> (*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.

[GRAPHIC: Participation timeline]

**Panel 6: Inside Right Panel**

[Graphic: Woman of Child-Bearing Potential]

*Your Privacy*

We understand the importance of your privacy. Your participation in the SORIATANE<sup>®</sup> (*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.**<sup>™</sup> 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.

[GRAPHIC: Soriatane logo]



[Graphic: Woman of Child-Bearing Potential]

## **SORIATANE<sup>®</sup> (acitretin) Do Your P.A.R.T.<sup>™</sup> Patient Survey Registration**

[Soriatane logo]

### **Purpose of the Survey**

The **SORIATANE<sup>®</sup> Do Your P.A.R.T.<sup>™</sup> (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 Soriatane use.

### **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 Soriatane treatment (MM/DD/YYYY)					

Signature

Month Day Year  
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 Capsules Do Your P.A.R.T Survey  
5150 McCrimmon Parkway  
Morrisville, NC 27560  
877-351-5495

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