

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 at 1-888-500-DERM (3376) or to the Food and Drug Administration (FDA) MedWatch program at 1-800-FDA-1088. The information I share will be kept confidential (private) and 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: _____

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?”.

CAUSES BIRTH DEFECTS <icon> DO NOT GET PREGNANT

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.**

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- **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 1-888-500-DERM (3376) 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
 - tetracyclinesThe 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[®] 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.**

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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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