MEDICATION GUIDE FOR PATIENTS
SORIATANE®
(soh-RYE-uh-tane)
(acitretin)
CAPSULES
• 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. A negative result shows you are not pregnant. Because it takes a few days after pregnancy test to show that you are pregnant, the first negative test may not ensure you are not pregnant. Do not take 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.
• 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
• You must use 2 effective forms of birth control (contraction) 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 the first 5 days after stopping Soriatane treatment
  • You use a contraceptive method that you have used consistently and correctly for at least 3 years. Before, during, and for at least 3 years after treatment
  • You can get a first birth control counseling session and pregnancy testing from your prescriber or family planning expert. Your prescriber can give you a Soriatane Patient Referral Form for this free service.
• You must use 2 effective forms of birth control (contraction) at the same time every time you repeat 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:
  • hormone tablets (birth control pills)
  • IUD (intrauterine device)
  • birth control pills that contain both estrogen and progesterone (combination oral contraceptives)
  • hormonal birth control products that are injected, implanted, or inserted in the body
  • birth control patch
• Secondary Forms (use with a Primary Form):
  • diaphragms with spermicide
  • latex condoms with 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 (contraction) at the same time, or if you get pregnant or miss your period, stop using Soriatane and call your prescriber right away.
• Consult your prescriber or “Emergency Contraprojection” (EC) if you have sex with a man without using 2 effective forms of birth control (contraction) at the same time, because EC works best if it is used within 1 or 2 days after sex. EC is not a replace-
• ment for your usual 2 effective forms of birth control (contraction) because it is not as effective as regular birth control methods.

SORIATANE® (acitretin)

What should I know about taking Soriatane?
Small amounts of Soriatane are found in the semen of males taking Soriatane. Based on 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.

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).

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 num-
• Stop taking Soriatane right away and contact your prescriber if you get preg-

What do I do if I am pregnant or breast feeding? If you do not know if you are pregnant or if you think you cannot become pregnant, unless 1 of the following is true for you:
• You had your womb (uterus) removed during the first 5 days after stopping Soriatane treatment
• You use a contraceptive method that you have used consistently and correctly for at least 3 years. Before, during, and for at least 3 years after treatment
• You can get a first birth control counseling session and pregnancy testing from your prescriber or family planning expert. Your prescriber can give you a Soriatane Patient Referral Form for this free service.
• You must use 2 effective forms of birth control (contraction) at the same time every time you repeat Soriatane treatment. You must use birth control for 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:
  • hormone tablets (birth control pills)
  • IUD (intrauterine device)
  • birth control pills that contain both estrogen and progesterone (combination oral contraceptives)
  • hormonal birth control products that are injected, implanted, or inserted in the body
  • birth control patch
Tell your prescriber if you have or ever had:
• diabetes or high blood sugar
• liver problems
• kidney problems
• high cholesterol or high triglycerides (fats 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 your other medicines work. Be especially sure to tell your prescriber if you are taking the following medicines:
• methotrexate
• intracranial
got the item
• alcoholism
• heart depression

Avoid alcohol.

Avoid pregnancy

Tell your prescriber if you have or ever have 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 prescriber may return. Do not treat 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 propylene-only birth control pills (“minipills”). This type of birth control pill should not be taken 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 symp-
\toms. Your medicine may harm 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?”

Postpartum 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 can be life threatening. 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 prob-
\tleneo and others claim to 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.
• Joint pain, blood clots, or stroke. These may be signs of a heart attack, blood clots, or stroke. Stop taking Soriatane and call your prescriber if you develop these problems. Medication that contains vitamin A (salmon, herring, cod liver oil, or vitamin supplements containing vitamin A) cannot be used while you are taking Soriatane. Ask your prescriber or pharmacist if you have any questions about dietary supplements that contain vitamin A.
• Night blindness. 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.
• Frequent urination, great thirst or hunger. Soriatane can affect blood sugar con-
\ttrol, even if you do not already have diabetes. These are some of the high blood sugars.
• Shortness of breath, dizziness, nausea, chest pain, weakness, trouble speak-
\ting, or feeling 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 reactions, call 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 (waxy) skin; nappy, dry nose, or nose
\tblodds. Your prescriber or pharmacist can recommend a lotion or cream to help treat drying or itching.
• 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 uncom-
\tersurable 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 monomogramming 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

Soriatane is 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. Tegison® is a registered trademark of Hoffmann-La Roche Inc.

Bi only
SORIATANE®
(acitretin)
25 mg

USUAL DOSAGE: See Package Insert.

Manufactured for
Connetics Corporation, Palo Alto, CA 94303 USA

Avoid exposing to high temperatures and humidity after the bottle is opened.

The interlocking C design is a trademark, and Soriatane is a registered trademark of Connetics Corporation.

Pharmacist: Provide a Medication Guide with each prescription.
Do not cover lot and expiry.

Each capsule contains 25 mg acitretin.

Rx only

30 Capsules
SORIATANE® (acitretin) 10mg
30 Capsules

Each capsule contains 10 mg acitretin.

USUAL DOSAGE: See Package Insert.

STORE AT 15° TO 25°C (59° TO 77°F).
PROTECT FROM LIGHT. AVOID EXPOSING TO HIGH TEMPERATURES AND HUMIDITY AFTER THE BOTTLE IS OPENED.

The interlocking C design is a trademark, and Connetics and Soriatane are registered trademarks, of Connetics Corporation.

PHARMACIST: PROVIDE A MEDICATION GUIDE WITH EACH PRESCRIPTION. DO NOT COVER LOT AND EXPIRY.
SORIATANE®
(acitretin)
25 mg

PROFESSIONAL COURTESY PACKAGE

Rx only
7 Capsules

Each capsule contains 25 mg acitretin.

USUAL DOSAGE: See Package Insert.

Manufactured for
Connetics Corporation, Palo Alto, CA 94303 USA
AW No.: AW-0258

NDC 63032-091-01

Store at 15°–25°C (59°–77°F). Protect from light. Avoid exposing to high temperatures and humidity after the bottle is opened.

The interlocking C design is a trademark of Connetics Corporation. Attention Pharmacist: Each patient is required to receive the enclosed Medication Guide. Do not cover lot and expiry.

™ ©

Each capsule contains 25 mg acitretin.

PROFESSIONAL COURTESY PACKAGE
SORIATANE®
(acitretin)
25 mg
Rx only
30 Capsules
Each capsule contains 25 mg acitretin.

USUAL DOSAGE: See Package Insert.

Manufactured for
Connetics Corporation, Palo Alto, CA 94303
USA
AW No.: AW-0259

Avoid exposing to high temperatures and humidity after the bottle is opened.

Pharmacist: Provide a Medication Guide with each prescription.
Do not cover lot and expiry.

The interlocking C design is a trademark, and Soriatane is a registered trademark, of Connetics Corporation.

Pharmacist: Provide a Medication Guide
with each prescription.
Do not cover lot and expiry.

Sixty-three thousand thirty-two
thirty-nine
twenty-five

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Manufactured for Connetics Corporation, Palo Alto, CA 94303
USA
AW No.: AW-0259

NDC 63032-091-25

CAUSES BIRTH DEFECTS
DO NOT GET PREGNANT

Each capsule contains 25 mg acitretin.

Pharmacist: Provide a Medication Guide
with each prescription.
Do not cover lot and expiry.