

General Guidelines



Pr SORIATANE[®]

(acitretin capsules)



SORIATANE®

(acitretin capsules)

GENERAL GUIDELINES

If you are a woman and your doctor has given you a prescription for SORIATANE®, please pay special attention to the IMPORTANT INFORMATION FOR FEMALES OF CHILDBEARING POTENTIAL section on page 6 of this guide, as SORIATANE® is a medication (retinoid) that can cause severe birth defects. You must also read the SORIATANE® Pregnancy Prevention Program Booklet that explains more information about the risk of having a baby with very severe birth defects and avoiding pregnancy while taking SORIATANE® and for **at least 3 years** after you stop. Do not breastfeed a baby during SORIATANE® treatment and for **at least 3 years** after stopping treatment. When you have read and understood the information in the SORIATANE® Pregnancy Prevention Program Booklet, you and your doctor will decide together if SORIATANE® is right for you. You will be asked to sign a consent form.

For male patients treated with SORIATANE®, available data, based on the level of maternal exposure from semen and seminal fluid indicate a minimal, if any, risk to an unborn child. Male patients should be reminded that they must not share their medication with anyone, particularly not females.

Read your prescription carefully and be sure to take exactly the number of capsules prescribed by your doctor. SORIATANE® capsules come in two dosages: 10 mg (brown and white) and 25 mg (brown and yellow). Your doctor may change your prescription from time to time, so it is especially important that you check the label after each refill to make sure you are taking the proper prescribed dosage.

- SORIATANE® should be taken with food or just after a meal. If you cannot take your SORIATANE® at the usual time, it may be taken later the same day. Do not take more SORIATANE® in one day than your doctor prescribed.
- If you miss a dose, take it as soon as you remember on the same day. Skip that dose if you do not remember until the next day.
- Do not consume alcohol (in drinks, food or medicines) during SORIATANE® treatment and for 2 months after stopping treatment with SORIATANE®.
- Protect SORIATANE® capsules from sunlight, heat and humidity, in its original package. SORIATANE® does not need to be refrigerated.
- **Always keep SORIATANE® out of the reach of children.**

OVERDOSE: In case of a drug overdose, contact your doctor, or a Poison Control Centre, or go to the Emergency Room of the hospital near you, immediately.

This medicine must not be shared with other people. Unused or expired drug (indicated on the package) should be returned to a pharmacy for proper disposal.

BEFORE TAKING SORIATANE®

TELL YOUR DOCTOR IF YOU:

- or any members of your family have: diabetes, liver disease, kidney disease, heart disease, high blood lipid levels, high pressure in the brain, depression, alcoholism, obesity, eye problems or wear contact lenses
- are sensitive or allergic to **acitretin** or other **retinoid drugs**, or **vitamin A** or other products containing vitamin A
- are sensitive to gelatin, glucose (liquid, spray-dried), iron oxide, microcrystalline cellulose, sodium ascorbate, titanium dioxide
- have high vitamin A levels (hypervitaminosis A)
- are taking an antibiotic (particularly tetracyclines)
- are taking phenytoin
- are taking methotrexate
- are taking glyburide or another sulfonylurea drug

Be sure to return to your doctor as scheduled. During the first months of treatment, blood tests may be necessary every 4 weeks until your doctor is able to determine your response to SORIATANE® treatment.

During the first months, blood tests may be necessary.

“During the first months, blood tests may be necessary”

WHEN TAKING SORIATANE[®]

During the first month of treatment, your skin symptoms may get worse before they get better. Occasionally, there may be an increase in redness and itching at first. This normally fades as treatment continues. It may take two or three months for you to see the full benefits of SORIATANE[®].

As with any medication, you'll probably have some side effects with SORIATANE[®]. Listed below are some common side effects, and recommendations on how to deal with them.

What you can expect

What you can do

Chapped Lips

Apply a lip ointment formulated to moisten and soften your lips.

Dry or Runny Nose

Apply a nasal lubricant to prevent nosebleeds. Use a humidifier in your bedroom.

Dry Eyes

Use an artificial tears product. If you wear contact lenses, choose a product that is compatible with your contacts.

Hair Thinning
Hair Loss
Abnormal Hair Texture

The extent of hair loss you may experience and whether or not your hair will return to normal after treatment cannot be predicted.

“It may take two or three months for you to see the full benefits of SORIATANE[®].”

CONTACT YOUR DOCTOR

- If you have any severe, unusual or troubling symptoms that appear during treatment
- If your side effects do not clear up in a few weeks after you stop taking SORIATANE[®]
- If you stop taking SORIATANE[®]
- If you have any questions

CONTACT YOUR DOCTOR AS SOON AS POSSIBLE

If you experience any of the following symptoms:

- Headaches, abdominal pain, diarrhea, nausea, or vomiting
- Persistent feeling of dry eyes, blurred vision, decrease in night vision, or other vision problems (Stop driving if you suddenly experience decreased night vision which is a rare side effect)
- Changes in mood
- Aches or pains in bones or joints, or difficulty in moving
- Redness or rash of skin
- Yellowing of the skin or eyes, and/or dark urine
- Flu-like symptoms

These symptoms may be early signs of rare but serious side effects that may possibly result in permanent effects.

SEEK EMERGENCY TREATMENT

If you experience any of the following symptoms:

- Shortness of breath, dizziness, nausea, chest pain, weakness or trouble speaking as these can be signs of a heart attack, or stroke.
- Swelling of a leg or ankle or foot as these can be signs of a blood clot.
- Worsening depression, suicidal thoughts or thoughts of self-harm.

These symptoms are life-threatening and require immediate medical attention.

The side effects described above are not a complete list and for any unexpected effects while taking SORIATANE[®] do contact your doctor or pharmacist.

MORE TO KNOW

Do not give blood	Do not donate blood while taking SORIATANE® and for at least 3 years after stopping SORIATANE® treatment. This is because your blood should not be given to a pregnant woman.
Do not take vitamin A supplements	Vitamin preparations and health food supplements that contain vitamin A may increase your chance of experiencing side effects while taking SORIATANE®.
Do not share SORIATANE® with anyone	SORIATANE® is a prescription product that can cause very serious side effects including severely deformed babies if taken during pregnancy or for at least 3 years after stopping SORIATANE® treatment. SORIATANE® should never be taken unless prescribed by a doctor.
Do not consume alcohol	Consumption of alcohol should be avoided while taking SORIATANE® and for two months after stopping treatment.
Protect yourself from the sun	SORIATANE® may increase your skin's sensitivity to excessive sunlight and to the effects of ultraviolet tanning lamps. Light therapy should only be used under medical supervision. A sunscreen of at least SPF 30 should be used.
See your doctor regularly	It is important for your doctor to see you regularly while you are taking SORIATANE®, preferably every month. Blood tests and other tests allow your doctor to evaluate your response to SORIATANE®.
Use caution when driving at night	If you experience decreased night vision, stop driving, and consult your doctor.

Tell all healthcare practitioners that you are taking SORIATANE® (such as other specialists, your family doctor, and your dentist).

SORIATANE® may interfere with other prescriptions or over-the-counter medicines and/or treatments.

WOMEN

IMPORTANT INFORMATION FOR FEMALES OF CHILDBEARING POTENTIAL TAKING SORIATANE® THAT YOU SHOULD DISCUSS WITH YOUR DOCTOR

Before you decide to take SORIATANE®, you must have discussed the consequences of becoming pregnant during SORIATANE® therapy with your doctor, and clearly understood those consequences. You will also be provided with the SORIATANE® Pregnancy Prevention Program Booklet to help you understand the importance of pregnancy prevention should you and your doctor decide together if SORIATANE® treatment is right for you. You will be asked to sign a consent form before you start treatment with SORIATANE®.

You must avoid becoming pregnant for 1 month before starting treatment, while you are taking SORIATANE® and for **at least 3 years** after you stop taking SORIATANE®. You must have 2 pregnancy tests (from a licensed laboratory) with negative results, the second test must not be older than 3 days before you start taking SORIATANE®.

You must use 2 methods of effective and complementary birth control for at least 1 month before, during, and for a period of **at least 3 years** after stopping SORIATANE® treatment.

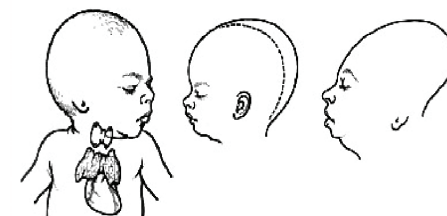
SORIATANE® should be started on the 2nd or 3rd day of your next menstrual period following a negative pregnancy test.

You should visit your doctor each month during treatment with SORIATANE® and obtain a pregnancy test (negative) in order to obtain a renewal of your prescription.

After stopping SORIATANE® treatment, pregnancy tests must be performed at 1-3 monthly intervals for a period of **at least 3 years** after the last dose is given.

Every time you start a new course of treatment with SORIATANE®, no matter how long the intervening period may have been, you must use effective and uninterrupted birth control during treatment and for **at least 3 years** after stopping SORIATANE®.

Do not breastfeed your baby while you are taking SORIATANE®, or for **at least 3 years** after stopping SORIATANE® treatment.



CONTACT YOUR DOCTOR IMMEDIATELY

If you become pregnant while taking SORIATANE® or **within 3 years** after stopping SORIATANE® treatment. There is a serious risk of severe birth deformities for the babies of women who are taking or who have taken SORIATANE®. You should discuss these risks with your doctor, as well as the desirability of continuing your pregnancy.

Information about SORIATANE® in this booklet has been adapted from the SORIATANE® Product Monograph, Allergan Inc., 85 Enterprise Blvd., Suite 500 Markham, ON L6G 0B5, 2016.

Important safety information about SORIATANE® and the SORIATANE® Pregnancy Prevention Program is available from:

Online: www.Soriatane.ca

or

**To speak to someone or to report an Adverse Reaction, please contact the
Aralez Pharmaceuticals Canada Inc. MEDICAL SAFETY INFORMATION LINE at
(toll-free) 1-866-391-4503**



 **SORIATANE®**

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Aralez Pharmaceuticals Canada Inc.
Mississauga, Ontario

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