

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **SORIATANE®**

Acitretin capsules

Read this carefully before you start taking **SORIATANE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about

Serious Warnings and Precautions

You **must** sign the informed consent form before you start taking SORIATANE.

Female patients:

Birth defects (deformed babies)

- **Do NOT** take SORIATANE if you are pregnant or want to become pregnant. SORIATANE can cause severely deformed babies.
- You must discuss **effective birth control** with your doctor before beginning treatment and you must use effective birth control without interruption as follows:
 - for at least one month before you start SORIATANE;
 - while you are taking SORIATANE; **and**
 - for at least 3 years after you stop taking SORIATANE (discuss this with your doctor); and
- Bear in mind that any method of birth control can fail. It is recommended that you either abstain from sexual intercourse or use two effective methods of birth control at the same time (discuss this with your doctor).
- Low dose progesterone-only may not be an effective method to prevent pregnancy during treatment with SORIATANE and is not recommended for use.
- **Do NOT take SORIATANE until you are sure that you are not pregnant:**
 - You must have 2 negative pregnancy tests before you start SORIATANE. The first test will be done at screening when SORIATANE treatment is under consideration. A second (confirmatory) test must be done within 3 days before the first dose is taken. Both tests must show you are not pregnant.
 - You must wait until the second or third day of your next menstrual period before you start SORIATANE.
- During treatment, you must have a pregnancy test at 28-day intervals in a licensed laboratory. The test must be no older than 3 days and show you are not pregnant before you can receive another prescription for SORIATANE.
- After stopping treatment, you must have pregnancy tests every 1-3 months for at least 3 years after your last dose.
- Every time you start a new course of treatment with SORIATANE, however long the intervening period may have been, you must use effective and uninterrupted birth control, during treatment and for **at least 3 years** after you stop taking SORIATANE.

- **Contact your doctor immediately if you do become pregnant while taking SORIATANE or after treatment has stopped.** You should discuss the serious risk of having a baby with severe birth deformities because you are taking or have taken SORIATANE, as well as available options, with your doctor.
- **Do NOT** breastfeed while taking SORIATANE and until at least 3 years after the treatment has stopped.

All patients:

- **Do NOT** consume alcohol while taking SORIATANE and for at least 2 months after the treatment has stopped.
- **Do NOT** donate blood while taking SORIATANE and until at least 3 years after the treatment has stopped. If someone who is pregnant gets your donated blood, the baby may be exposed to SORIATANE and be born with birth defects.

SORIATANE can cause serious side effects, including:

- **Liver problems**
 - Cases of jaundice, toxic hepatitis (inflammation of the liver) and liver injury have been reported in patients taking SORIATANE.
 - Before starting treatment and during treatment with SORIATANE, your healthcare professional will do blood tests to check how your liver is working.
- **Pseudotumor cerebri (benign intracranial hypertension).** This is a condition where there is an increased pressure in the brain.
- **Mood changes (including irritability, aggression, depression, suicide and thoughts of suicide and self-harm)**
 - Before you take SORIATANE, your healthcare professional will assess you for mood changes, including depression.
 - Tell your healthcare professional right away if you have any symptoms of new depression or worsening depression.
- **Psychotic disorder (hallucinations or delusions):** This may cause you to experience hallucinations (seeing or hearing things) or delusions (have false beliefs).

What is SORIATANE used for?

SORIATANE (acitretin) is used in the treatment of:

- Severe psoriasis
- Other disorders of keratinization in adult patients who have not responded to standard treatments.

How does SORIATANE work?

SORIATANE (acitretin) is a retinoid. It works by leading to a more normal pattern of growth for skin cells.

What are the ingredients in SORIATANE?

Medicinal ingredients: Acitretin

Non-medicinal ingredients: Gelatin, glucose (liquid spray-dried), microcrystalline cellulose, sodium ascorbate, capsule (gelatin, iron oxide black, iron oxide red, iron oxide yellow and titanium dioxide) and printing ink (ammonium hydroxide, black iron oxide, isopropyl alcohol, n-butyl alcohol, propylene glycol and shellac).

SORIATANE comes in the following dosage forms:

Capsules: 10 mg and 25 mg

Do not use SORIATANE if you:

- are pregnant, or plan to become pregnant
- become pregnant while taking SORIATANE. You must stop taking SORIATANE immediately. See “**Serious warnings and precautions**” box.
- are breastfeeding.
- are allergic to acitretin, or any of the other ingredients in SORIATANE,
- are allergic to other retinoids, or Vitamin A, or its metabolites,
- consume alcohol (in drinks, food or medicines),
- have severe liver problems.
- have severe kidney problems.
- have consistent high blood lipid levels
- take tetracyclines, medicines used to treat bacterial infections.
- take methotrexate, medicine used to treat cancer and other conditions caused by overactive immune system.
- have high vitamin A levels (hypervitaminosis A).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SORIATANE. Talk about any health conditions or problems you may have, including if you:

- have high cholesterol or triglycerides.
- have high blood sugar, or have a family history of diabetes. You may need to check your blood sugar levels more frequently at the beginning of treatment.
- have liver problems
- have kidney problems
- have or have had depression, or have a family history of depression.
- have eye problems or wear contact lenses. SORIATANE may cause dry eyes, light sensitivity, or other eyes problems.

Other warnings you should know about:

- **SORIATANE Pregnancy Prevention Program**
You should have been counselled using the manufacturer’s SORIATANE Pregnancy Prevention Program which includes:
 - Comprehensive information about the risks of this drug
 - A line drawing of a deformed baby
 - A checklist of the criteria you had to meet before receiving this drug

- Detailed information on birth control options
- A chart outlining the SORIATANE Pregnancy Prevention Program
- An informed consent form for you to review and sign (for males and females)

If you were not counselled using the SORIATANE Pregnancy Prevention Program, please contact the marketing agent for Canada, Aralez Pharmaceuticals Canada Inc. Medical Safety Information Line at (toll-free) 1-866-391-4503.

- **Skin**

- Avoid prolonged exposure to sunlight or sun lamps while taking SORIATANE. Use protective clothing or hat or sunscreen with SPF 30 or more. SORIATANE may make your skin more sensitive to UV light.
- Avoid cosmetic procedures that smooth your skin (such as waxing, dermabrasion or laser procedures), while taking SORIATANE and for a period of time after stopping. SORIATANE may cause scarring or inflammation of the skin from these procedures. Check with your healthcare professional for advice about when you can have cosmetic procedures.
- Avoid the use of anti-acne agents that exfoliate your skin since it can irritate your skin.
- You should use a skin moisturizing ointment or cream and a lip balm while taking SORIATANE. This is because SORIATANE can make your skin and lips dry.

- **Check-ups and testing**

- You will have regular visits with your healthcare professional during your treatment with SORIATANE. They will:
 - Do blood tests to check blood lipid levels (cholesterol, triglycerides), sugar levels and liver health.
 - Assess you for mood changes.
 - Examine you for signs of bone abnormalities and vision problems.
- In female patients, your healthcare professional will ask you to have pregnancy tests before treatment with SORIATANE and regularly during and after treatment. During treatment, a pregnancy test is needed every 28 days. After stopping treatment, pregnancy tests must be done every 1-3 months for 3 years after your last dose.

- **Driving and using machinery**

- SORIATANE may change your vision and ability to drive at night. Be cautious when driving any vehicles or doing tasks that require special attention, especially at night.

- **Children (younger than 18 years of age)**

- You should not take SORIATANE if you are younger than 18 years of age.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions:

Serious drug interactions with SORIATANE include:

- Vitamin A or retinoids.
- Methotrexate. Taking SORIATANE with methotrexate may increase your risk of hepatitis.
- Tetracyclines. Taking SORIATANE with tetracyclines may increase your risk of increased pressure in the skull (intracranial pressure).
- Alcohol. It convert SORIATANE to etretinate, a chemical that also causes birth defects and stays in the body longer.

The following may also interact with SORIATANE:

- Phenytoin, medicine used to treat seizures
- Glyburide, or a sulfonylurea, medicines used to treat diabetes
- St John's Wort
- Low dose birth control pills. Low dose birth control pills that contain progesterone only (mini pills) may not work while you are taking SORIATANE.

How to take SORIATANE:

- Always take SORIATANE exactly as your healthcare professional tells you.
- Take by mouth once daily with food or after a meal.

Usual dose:

Your dose will depend on your medical condition and the recommendations of your healthcare professional. Your healthcare professional may change or stop your dose depending on how well SORIATANE is working for you.

For Severe psoriasis: starting dose of 25 mg once daily; maintenance daily dose from 25 mg to 50 mg; maximum daily dose of 75 mg.

For Other disorders of keratinization: 10 mg once daily; maximum daily dose of 50 mg

Overdose:

If you think you, or a person you are caring for, have taken too much SORIATANE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

- If you miss a dose of SORIATANE, take it as soon as you remember on the same day. However, if it is almost time for your next dose, skip the missed dose and take the next dose at your regular time.
- Do NOT take a double dose to make up for a missed dose.

What are possible side effects from using SORIATANE?

These are not all the possible side effects you may have when taking SORIATANE. If you experience any side effects not listed here, tell your healthcare professional.

- Back pain, bone pain or muscle pain
- Brittle nails
- Bleeding or inflammation of the gums, or inflammation of the mucous lining of the mouth
- Chills, increased sensitivity to touch.
- Dry eyes, particularly if you wear contact lenses
- Dry mouth, chapped lips, runny or dry nose
- Decreased or increased appetite
- Ear problems such as pain, wax build-up, or buzzing in the ear
- Eye problems such as light sensitivity, pain, impaired vision
- Hair loss or abnormal hair texture. Whether all your hair will return to normal after treatment cannot be predicted.
- Infections, including skin around the fingernail
- Inflammation along the edge of the eyelid (blepharitis), inflammation or infection of the membrane lining the eyelids (conjunctivitis)
- Nose bleeds
- Skin problems such as cold sweat, excessive sweating, sensitivity to sunlight, inflamed, ulcerated, and oily or cracked skin.
- Tiredness, pain, thirst
- Trouble sleeping

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Abdominal pain: Stomach pain			√
Diarrhea			√
Headache			√
Nausea			√
Vomiting			√
Skin Atrophy: Fragile skin	√		
Alopecia: Hair loss	√		
Chelitis: Inflamed lips	√		
Pruritis: Itching	√		
Skin exfoliation: Peeling of Fingertips, Peeling skin all over the body	√		
Rash erythematous: Redness or Rash		√	
Sticky Skin: Skin is sticky	√		
Hearing problems: impaired hearing, ringing in the ears		√	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Blurred vision: Cloudy vision or difficulty focusing eyes			√
Dry eye: Persistent feeling of dry eyes		√	
Jaundice: Yellowing of the skin or eyes and/or flu-like symptoms and/or dark urine			√
Heart Problems: Shortness of breath, Weakness, Nausea, Dizziness, Chest Pain, and Trouble Speaking. These can be signs of heart attack or stroke.			√
Peripheral oedema: Swelling of a leg, ankle, foot or arm. These can be signs of blood clot			√
VERY RARE			
Visual impairment: Decreased night vision		√	
Arthralgia: Aches or Pain in Joints or Difficulty Moving. Bone changes have been detected by X-ray examination in patients taking SORIATANE. The extent of any harm from these changes is not presently known		√	
Serious Skin Reactions such as erythema multiforme (EM), Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN): Severe red / purple rash, fever or not feeling well, red or inflamed eyes, facial and tongue swelling, blisters, peeling skin, multiple lesions and sores, especially in your mouth, nose, eyes and genitals.			√
UNKNOWN FREQUENCY			
Allergic reactions: Rash, hives, itching, swelling of the face, lips, tongue or throat, difficulty breathing or swallowing			√

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Capillary leak syndrome: Sudden swelling in one part or all over your body, weight gain, fever, light-headedness, feeling faint or muscle aches			√
Exfoliative dermatitis: Red, swollen, itchy, painful or peeling skin. It can begin in a small area and then spread over large areas of your body.			√
Madarosis: Eyelash and sometimes eyebrow loss		√	
Rectal haemorrhage: Rectal bleeding			√
Suicidal thoughts: Thoughts of suicide or self-harm			√
Worsened emotional or behavioral problems: Worsening depression, Changes in Mood (such as becoming depressed, feeling sad or having crying spells), Aggressive behaviour (such as, temper outbursts, thoughts of violence), psychotic disorder (hallucinations or delusions)			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at 15 to 25 °C in the original package. Protect from heat, light and moisture.
- Keep out of reach and sight of children.
- Do not use after the expiry date (EXP) shown on the package.

If you want more information about SORIATANE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.aralez.com, or by calling 1-866-391-4503.
- Important safety information about SORIATANE and the SORIATANE Pregnancy Prevention Program is also available from: Online: www.Soriatane.ca

This leaflet was prepared by Allergan Inc.

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