

PART III: CONSUMER INFORMATION

PrSORIATANE®
(acitretin capsules)
10 mg and 25 mg

This leaflet is part III of a three-part "Product Monograph" published when SORIATANE® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SORIATANE®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is 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.

What it does:

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

When it should not be used:

SORIATANE® can cause severely deformed babies. In order to take this drug, a female patient must use an effective birth control method 4 weeks before the start of treatment, during treatment and until at least 3 years after the last dose of SORIATANE®.

Do not consume alcohol during the treatment and until at least 2 months after the last dose of SORIATANE®.

Do not breastfeed during treatment and until at least 3 years after the last dose of SORIATANE®.

Do not use SORIATANE® if you:

- Are allergic to acitretin, or other retinoids, or Vitamin A, or its metabolites, or any of the other ingredients in SORIATANE®
- Are pregnant or plan to get pregnant
- Are breastfeeding
- Have severe liver or kidney disease
- Have consistent high blood lipid levels
- Take tetracyclines
- Take methotrexate
- Have high vitamin A levels (hypervitaminosis A)

Information for the patient (male and female):

SORIATANE® can cause severely deformed babies if it is taken by a female before or during pregnancy and for at least 3 years after stopping.

What the medicinal ingredient is:

Acitretin

What the non-medicinal ingredients are (in alphabetical order):

Gelatin, glucose (liquid spray-dried), iron oxide, microcrystalline cellulose, sodium ascorbate, titanium dioxide.

What dosage forms it comes in:

Each SORIATANE® capsule contains either 10 mg or 25 mg of acitretin.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

You must avoid becoming pregnant while you are taking SORIATANE® and until at least 3 years after you stop taking SORIATANE® (discuss this with your doctor).

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
- bearing 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 (Micronor 28) 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 (with a negative result) is obtained at screening when SORIATANE® treatment is under consideration. A second (confirmatory) test (with a negative result) must be obtained not older than 3 days before the first dose.
- 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. A negative pregnancy test, from a licensed laboratory, not older than 3 days is mandatory 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.

Male and female patients should avoid consuming alcohol while taking SORIATANE[®] and until at least 2 months after the treatment has stopped.

Male and female patients should not donate blood while taking SORIATANE[®] and until at least 3 years after the treatment has stopped.

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.

Before taking SORIATANE[®], talk to your doctor if you have any of the following conditions:

- high cholesterol or triglycerides
- high blood sugar
- liver or kidney problems
- mood changes
- skin problems
- high pressure in the brain (intracranial hypertension)
- eye problems or wear contact lenses. SORIATANE[®] may cause dry eyes, light sensitivity, or other eyes problems.

While taking SORIATANE[®] you should avoid prolonged exposure to sunlight or sun lamps. Use protective clothing or hat or sunscreen with SPF 30 or more.

SORIATANE[®] is not recommended for use in children.

INTERACTIONS WITH THIS MEDICATION

Before taking SORIATANE[®] tell your doctor or pharmacist about all other medications you take including medications that you bought without prescription, vitamins, and natural products. Particularly if you are taking the following:

- Vitamin A
- Methotrexate
- Tetracyclines, phenytoin
- Glyburide, or a sulfonylurea
- St John's Wort
- Alcohol because it can convert SORIATANE[®] to etretinate, a chemical that also causes birth defects and stays in the body longer.
- Low dose of progesterone-only contraceptive (Micronor 28)

PROPER USE OF THIS MEDICATION

You should take SORIATANE[®] as told by your doctor.

Usual dose:

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

Take SORIATANE[®] once daily with food or after a meal.

OVERDOSE:

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

MISSED DOSE:

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects and what to do about them:

The first few weeks before you begin to see any healing, you may begin to have some side effects.

Side effects of SORIATANE® include the following:

Very common:

Dry eyes, particularly if you wear contact lenses;
 Dry mouth, chapped lips, runny or dry nose;
 Dry skin, peeling of fingertips and/or palms and soles, itchy skin, rash, sticky skin, brittle nails;
 Chills, joint pain, increased sensitivity to touch.

Most patients experience some degree of hair loss or abnormal hair texture but the condition varies among patients. The extent of hair loss that you may experience and whether or not all your hair will return to normal after treatment cannot be predicted.

Common:

Nosebleeds;
 Ear problems such as pain, wax build-up, or buzzing in the ear;
 Eye problems such as blurred vision, light sensitivity, pain, impaired vision;
 Inflammation along the edge of the eyelid (blepharitis), inflammation or infection of the membrane lining the eyelids (conjunctivitis);
 Tiredness, pain, thirst;
 Swelling of leg, foot, ankle (oedema);
 Bleeding or inflammation of the gums, or inflammation of the mucous lining of the mouth;
 Nausea or abdominal pain;
 Infections, including skin around the finger nail;
 Decreased or increased appetite;
 Back pain, bone pain or muscle pain;
 Headache, trouble sleeping;
 Skin problems such as cold sweat, excessive sweating, sensitivity to sunlight, inflamed, ulcerated, and oily or cracked skin.

Uncommon:

Decrease in night vision, or other eye problems, impaired hearing.

These are not all the possible side effects of SORIATANE®. For more information, ask your prescriber or pharmacist.

SERIOUS SIDE 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, foot, ankle or arm as these can be signs of a blood clot.
- Worsening depression, suicidal thoughts or thoughts of self-harm.

OTHER SERIOUS SIDE EFFECTS:

- Headaches, abdominal pain, diarrhea, rectal bleeding, nausea, vomiting, blurred vision, other visual problems.
- Decrease in night vision.
- Persistent feeling of dry eyes
- Yellowing of the skin or eyes and/or dark urine, flu-like symptoms.

Aches or pains in bones or joints, or difficulty in 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 SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Abdominal pain			√
	Diarrhea			√
	Headache			√
	Nausea			√
	Vomiting			√
	Fragile skin	√		
	Hair loss	√		
	Inflamed lips	√		
	Itching	√		
	Peeling of Fingertips	√		
	Peeling skin all over the body	√		
	Redness or Rash			√
	Sticky Skin	√		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist	
		Only if severe	In all cases		
Uncommon	Blurred vision, Dizziness Persistent feeling of dry eyes		√	√ √	
	Yellowing of the skin or eyes and/or flu-like symptoms and/or dark urine			√	
	Shortness of breath, Weakness, Nausea, Dizziness	√ √		√ √	
	Chest Pain, Trouble Speaking, Swelling of a leg, ankle, foot or arm			√ √ √	
	Rare/Very Rare	Decreased night vision		√	
		Impaired Hearing		√	
		Aches or Pain in Joints or Difficulty Moving		√	
		Rectal bleeding			√
	Changes in Mood/ depression, Thoughts of suicide, Aggressive behaviour			√ √ √	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Unknown frequency	Allergic reactions: Rash, hives, itching, swelling of the face, lips, tongue or throat, difficulty breathing or swallowing			√
	Capillary leak syndrome: Sudden swelling in one part or all over your body, weight gain, fever, lightheadedness, 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		√	

This is not a complete list of side effects. For any unexpected effects while taking SORIATANE® contact your doctor or pharmacist.

THIS SUMMARY DOES NOT CONTAIN ALL KNOWN INFORMATION ABOUT SORIATANE®. TALK TO YOUR DOCTOR IF YOU HAVE ANY QUESTIONS.

HOW TO STORE IT

Protect SORIATANE® capsules from sunlight, heat and humidity. Store in original package. SORIATANE® does not need to be refrigerated. SORIATANE® should not be used after the expiry date (EXP) shown on the package.

Keep SORIATANE® and all medications out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.aralez.com>

or by contacting the marketing agent for Canada, Aralez Pharmaceuticals Canada Inc., MEDICAL INFORMATION SAFETY LINE (toll-free) 1-866-391-4503.

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

- Online: www.Soriatane.ca

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