



GENERAL MEDICATION GUIDE FOR PATIENTS

TARO-Acitretin

PREGNANCY PREVENTION PROGRAM





TARO-Acitretin Capsules

IMPORTANT PATIENT INFORMATION

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TARO-Acitretin

Why Your Doctor Has Prescribed Taro-Acitretin

Taro-Acitretin is used in adult patients to treat severe psoriasis. Psoriasis is a skin condition that is caused by skin cells that multiply up to ten times faster than normal and gather on the skin's surface. Taro-Acitretin is also used in adult patients to treat other similar skin diseases.

Acitretin belongs to a family of drugs called retinoids. It works by slowing down skin cells that are multiplying at a very high rate. This re-establishes a more normal pattern of growth.

What You Must Know Before Taking Taro-Acitretin

Especially for Women of Childbearing Potential

Taro-Acitretin can cause severe birth defects (deformed babies). A female patient must use effective birth control for at least four weeks before the start of treatment, during treatment, and until at least three years after the last dose of Taro-Acitretin. Please refer to p. 3, "Pregnancy Prevention Instruction."

Patients must not consume alcohol during treatment and for at least two months after the last dose of Taro-Acitretin.

Women must not breastfeed during treatment and for at least three years after the last dose of Taro-Acitretin.

For Both Women and Men

Do NOT use Taro-Acitretin if you:

- are allergic to acitretin, or other retinoids, or Vitamin A, or its metabolites, or any of the other ingredients in Taro-Acitretin
- are pregnant or plan to get pregnant
- are breastfeeding
- have severe liver or kidney disease
- have consistent high blood lipid (cholesterol, triglycerides) levels
- are taking phenytoin
- take tetracyclines
- take methotrexate
- have high vitamin A levels (hypervitaminosis A)

Before taking Taro-Acitretin, speak with 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 other than those the drug has been prescribed for
- High pressure in the brain (intracranial hypertension)
- Eye problems or wear contact lenses (Taro-Acitretin may cause dry eyes, light sensitivity, or other eye problems)

Blood tests may be necessary every four weeks during the first months of treatment with Taro-Acitretin in order to determine your response to the drug. Be sure to keep all of your appointments with your doctor as scheduled.



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Pregnancy Prevention Instruction

Taro-Acitretin can cause severely deformed babies.

You must avoid becoming pregnant while you are taking Taro-Acitretin and for at least three years after you stop taking the drug.

You must discuss effective birth control with your doctor before starting to take Taro-Acitretin, and **effective birth control** must be continued without interruption as follows:

- For at least one month before you start taking Taro-Acitretin
- While you are taking Taro-Acitretin
- For at least three years after you stop taking Taro-Acitretin

Because any birth control method can fail, it is recommended that you either abstain from sexual intercourse or use two effective methods of birth control at the same time.

A low-dose progesterone-only birth control pill (mini-pill) may not be an effective method to prevent pregnancy during treatment with Taro-Acitretin and is not recommended for use.

You must be absolutely sure that you are not pregnant before starting to take Taro-Acitretin:

- You must have two negative pregnancy tests before you start taking Taro-Acitretin. The first test (with a negative result) should be completed at time of screening when Taro-Acitretin is first being considered. The second test should be conducted to confirm the negative result of the first test no more than three days before the first dose of Taro-Acitretin is scheduled.

- You must wait until the second or third day of your next menstrual period before you start taking Taro-Acitretin unless you are using treatment that prevents you from having periods (e.g., extended hormonal contraception, progesterone intrauterine device). Talk to your doctor about this if you aren't sure.
- While taking Taro-Acitretin, you must have pregnancy tests at 28-day intervals. Before receiving another prescription for Taro-Acitretin, you must have a negative pregnancy test not older than three days from a licensed laboratory.
- After stopping treatment, you must have pregnancy tests every one to three months for **at least three years** after your last dose.
- Every time a new course of treatment with Taro-Acitretin is started, you must use effective and uninterrupted birth control one month before starting treatment, during treatment, and at least three years after you stop taking Taro-Acitretin.

You must discuss pregnancy prevention and the consequences of becoming pregnant while taking Taro-Acitretin with your doctor. You will be provided with the "Preventing Pregnancy and Precautions Guide for Patients" in order to help you and your doctor decide together if Taro-Acitretin is the right medication for you.

You will be asked to sign a consent form to acknowledge that you understand the risks associated with taking Taro-Acitretin before starting treatment.

If you do become pregnant while taking Taro-Acitretin or within three years after treatment has stopped, contact your doctor immediately. You should discuss the serious risk of having a baby with severe birth deformities, as well as available options, with your doctor.



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How to Take Taro-Acitretin

Your doctor and pharmacist should inform you of the number of Taro-Acitretin capsules you should take once a day, the strength of the capsules (either 10 mg or 25 mg), and when you should take them.

Read your prescription label carefully. If the information does not agree with what your doctor and pharmacist discussed with you, contact your doctor or pharmacist before taking the medication.

- Taro-Acitretin 10 mg capsules are brown and white.
- Taro-Acitretin 25 mg capsules are brown and yellow.

Check your prescription each time you receive a refill. If there are any changes to the instructions or the appearance of the pills that you were not made aware of, be sure to discuss this with your pharmacist.

- Taro-Acitretin should be taken once daily with food or after a meal.
- If you miss a dose, you can take it as soon as you remember on the same day. Skip the dose if you do not remember until the next day.

In case of drug overdose, contact your doctor or a poison control centre, or go to the emergency room of the hospital closest to you immediately.

Protect Taro-Acitretin capsules from sunlight, heat, and humidity. Store the capsules in the original package. The medication should not be used after the expiry date shown on the package.



The Journey to Healthier Skin – What to Expect

It may take two or three months before you see the full benefits of Taro-Acitretin.

During the first few weeks of taking Taro-Acitretin, it is normal that you may have some side effects before you begin to see any healing.

Following are some of the common side effects and what you can do about them:

- Dry eyes (especially if you wear contact lenses)
 - Use an artificial tears product (drops or gel). If you wear contact lenses, be sure to use a product that is compatible.
- Chapped lips
 - Apply a lubricating lip cream or balm. Breathe through your nose as much as possible as mouth breathing can worsen the dry lip problem.
- Dry or runny nose
 - Use a nasal lubricant (e.g., dab of petroleum jelly). Use a cool mist humidifier in your room.

Additional common side effects include:

- Nosebleeds
- Ear problems (e.g., pain, wax buildup, or buzzing in the ear)
- Eye problems such as blurred vision, light sensitivity, pain, impaired vision
- Inflammation along the edge of the eyelid (blepharitis) or infection of the membrane lining the eyelids (conjunctivitis)
- Tiredness, pain, thirst
- Swelling of leg, foot, ankle



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- Bleeding or inflammation of the gums, or inflammation of the mucous lining of the mouth
- Nausea or abdominal pain
- Infections, including skin around the fingernail
- Decreased or increased appetite
- Back pain, bone pain, or muscle pain
- Headache, trouble sleeping
- Skin problems such as cold sweats; excessive sweating; sensitivity to sunlight; inflamed, ulcerated, oily, or cracked skin

Most people that take Taro-Acitretin experience hair loss or abnormal hair texture to some degree, but this varies among patients. The amount of hair loss that you might experience and whether or not your hair will return to normal after treatment cannot be predicted.

Serious Side Effects and When to Call Your Doctor

Stop taking Taro-Acitretin and call your doctor as soon as possible under the following circumstances:

- Abdominal pain
- Diarrhea
- Headache
- Nausea or vomiting
- Blurred vision, decreased night vision
- Dizziness
- Weakness
- Persistent feeling of dry eyes, eyelash and sometimes eyebrow loss
- Redness or rash on skin
- Yellowing of the skin or eyes and/or flu-like symptoms and/or dark urine, flu-like symptoms
- Rectal bleeding
- Aches or pains in bones or joints, or difficulty moving
- Red, swollen, itchy, painful, or peeling skin that can begin in a small area and then spread over large areas of your body

Stop taking Taro-Acitretin and seek emergency assistance immediately if you experience any of the following symptoms:

- Signs of a potential heart attack or stroke such as chest pain, shortness of breath, dizziness, nausea, trouble speaking
- Signs of a potential blood clot such as swelling of a leg, ankle, foot, or arm
- Suicidal thoughts or thoughts of self-harm, worsening depression, aggressive behaviour, changes in mood



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- Allergic reactions: rash, hives, itching, swelling of the face, lips, tongue, or throat, difficulty breathing or swallowing
- Capillary leak syndrome: swelling in one part or all over your body, weight gain, fever, lightheadedness, feeling faint, or muscle aches

Side effects other than those listed may occur. If you experience any unexpected side effects while taking Taro-Acitretin, contact your doctor or pharmacist.

Additional Information

DO NOT take Vitamin A supplements.

- Vitamin A supplements and health food preparations containing extra Vitamin A may increase your risk of experiencing side effects with Taro-Acitretin.

DO NOT drink alcohol.

- Do not consume alcohol while taking Taro-Acitretin and for two months after stopping the medication because it converts acitretin to another chemical that also causes birth defects and stays in your body for a longer period of time.

DO NOT give blood.

- Do not give blood while taking Taro-Acitretin and for **at least three years** after stopping the medication, as it must not be given to a pregnant woman.

SUNLIGHT PROTECTION is very important.

- Always use sunscreen with at least SPF 30 protection when out in the sun. Taro-Acitretin may increase sensitivity of the skin to excessive sunlight and to the effects of ultraviolet tanning lamps. Light therapy should be used only under medical supervision.

ATTEND ALL MEDICAL APPOINTMENTS.

- It is important to see your doctor regularly (preferably every month) while taking Taro-Acitretin. Your doctor will assess how you are doing and evaluate blood tests that you will need during treatment.

BE CAUTIOUS WHEN DRIVING.

- In some people Taro-Acitretin can cause blurred vision and/or decrease in night vision. If you experience any difficulties with vision, stop driving and speak with your doctor.

TELL ALL HEALTHCARE PRACTITIONERS that you are taking Taro-Acitretin.

- Healthcare practitioners such as doctors, pharmacists and dentists must know that you are taking Taro-Acitretin, as the drug may interfere with other medicines or treatments.



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In Summary

Taro-Acitretin is a drug that is used in adult patients to treat severe psoriasis and other similar skin diseases. It is extremely important that you understand the risks associated with taking Taro-Acitretin:

- Ensure that your doctor discusses the consequences of pregnancy while taking Taro-Acitretin and for three years after stopping the medication as well as the best ways to prevent pregnancy. Ensure that you have read and completely understood the "Preventing Pregnancy and Precautions Guide for Patients." If there is anything in the guide that you do not understand, or if you have any questions, be sure to speak with your doctor or pharmacist.
- Ensure that you read and completely understand the information concerning risks associated with taking Taro-Acitretin in this general medication guide. If there is anything you don't understand, or if you have any questions, be sure to speak with your doctor or pharmacist.
- You will be asked to sign a consent form indicating that you understand all of the risks associated with taking Taro-Acitretin capsules.

Contact your doctor immediately if you become pregnant while taking Taro-Acitretin or within three years after stopping treatment.

Important safety information about Taro-Acitretin and the Pregnancy Prevention Program is available from Taro-acitretin.ca.

- To speak to someone or to report an adverse reaction, please contact the Taro Pharmaceutical Industries Ltd. Customer Service Department at 1-800-268-1975.

Information about Taro-Acitretin in this guide has been adapted from the "Taro-Acitretin Product Monograph," Taro Pharmaceutical Industries Ltd.