

# PREVENTING PREGNANCY AND PRECAUTIONS GUIDE FOR PATIENTS



**TARO-Acitretin**

PREGNANCY PREVENTION PROGRAM





# TARO-Acitretin

## Why a Preventing Pregnancy and Precautions Guide?

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 which re-establishes a more normal pattern of growth.

**Taro-Acitretin must not be used by women who are at risk of becoming pregnant**, because the drug may cause severe birth defects (deformed babies).

This Preventing Pregnancy and Precautions Guide has been developed to provide you with information to reduce the risk of becoming pregnant during Taro-Acitretin treatment and for at least three years after stopping Taro-Acitretin.

## What You Should Know Before Taking Taro-Acitretin

- Do not become pregnant during treatment with Taro-Acitretin and **for at least three years** after stopping Taro-Acitretin.
- Do not breastfeed during treatment with Taro-Acitretin **and for at least three years** after stopping Taro-Acitretin.
- 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.

- Do not consume alcohol in drinks, food, or medicines while taking Taro-Acitretin and for two months after stopping the medication, because alcohol converts acitretin to another chemical that also causes birth defects and stays in your body for a long period of time.
- Do not share Taro-Acitretin with other people, even if they have the same condition or symptoms as you do.

**You must also read the "General Medication Guide for Patients" to determine if Taro-Acitretin is the right medicine for you.**

## Ensuring Pregnancy Prevention Before, During, and After Taro-Acitretin Treatment

Because Taro-Acitretin can cause severely deformed babies, you must not use Taro-Acitretin if you are pregnant, planning to become pregnant, or may become pregnant during Taro-Acitretin treatment, and for at least three years after stopping Taro-Acitretin.

You must confirm that you are not pregnant and use effective birth control before starting Taro-Acitretin.

## Confirmation of Not Being Pregnant

- Before starting Taro-Acitretin capsules, you must have received two negative pregnancy tests from a licensed laboratory. The second negative test must have been completed within the three days before starting to take Taro-Acitretin.
- You should not start taking Taro-Acitretin until the second or third day of your next menstrual period.
- While taking Taro-Acitretin you should have pregnancy tests conducted at 28-day intervals and visit your doctor monthly. Before renewing your prescription for Taro-Acitretin, a negative pregnancy test conducted not more than three days earlier is required.



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## Effective Birth Control

- Discussion of effective birth control is required before starting treatment with Taro-Acitretin. Unfortunately, any birth control method can fail, so it is important to use two birth control methods that act in different ways at the same time or completely abstain from sexual intercourse. If using two different methods of birth control, they must be used for at least one month before starting Taro-Acitretin, during treatment, and for three years after stopping Taro-Acitretin.
- It is important that St. John's wort not be used by women using hormonal contraception as one of their methods of birth control. This is because it has been found that St. John's wort may reduce the effectiveness of birth control that relies on the actions of hormones.
- Low-dose progesterone-only products (mini-pills) should be avoided as a source of contraception, as they may not be an effective method to prevent pregnancy.

## Deciding On Effective Birth Control

**Taro-Acitretin may cause severe birth defects (deformed babies).** Therefore, it is very important to prevent pregnancy before and during Taro-Acitretin treatment and for at least three years after stopping Taro-Acitretin.

If you are of childbearing potential, you and your doctor must agree on effective birth control, which includes a primary birth control method combined with one of the secondary birth control methods.

### Primary birth control methods include:

- Birth control pills (but not "mini-pills")
- Birth control patch
- Intrauterine device (IUD)
- Injected, implanted, or inserted hormonal birth control products
- Tubal ligation (having your tubes tied)
- Vasectomy by your partner

### Secondary birth control methods include:

- Diaphragm with spermicide
- Cervical cap with spermicide
- Latex condom with or without spermicide

To obtain confidential birth control counselling, you may contact Action Canada for Sexual Health & Rights 24-hour Canada-wide Access line at 1-888-642-2725.

- There are many primary and secondary birth control methods available.
- You and your doctor should discuss all available methods and decide which primary and secondary method are best for you.



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## Additional Warnings and Precautions

- You must not breastfeed while taking Taro-Acitretin and for at least three years after you have stopped taking the medication.
- If your period is abnormal in length or intensity, or if you do get pregnant while taking Taro-Acitretin or within three years after stopping treatment, be sure to contact your doctor immediately. You need to talk with your doctor about the serious risks associated with having a baby with severe birth deformities and decide whether or not you wish to continue with the pregnancy.
- Alcohol must not be ingested in drinks, food or medicines by women of childbearing potential taking Taro-Acitretin and for two months after stopping the medication. Women taking Taro-Acitretin are also referred to the "General Medication Guide for Patients" for more information.

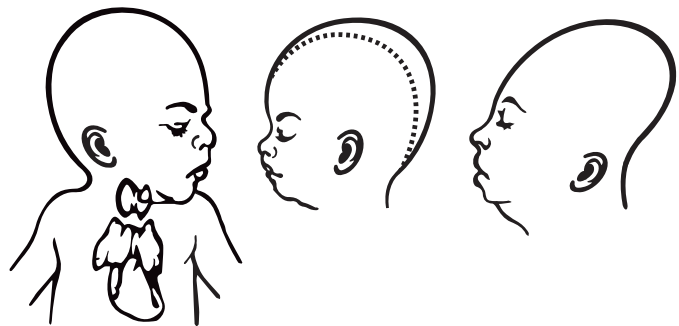
## Informing Your Sexual Partner of Risks Associated with Taro-Acitretin Use

It is vital that your sexual partner also understand the severe birth defect risks associated with pregnancy and the use of Taro-Acitretin. For this reason it is strongly recommended that your sexual partner read all of the information provided to you with respect to the Pregnancy Prevention Program.

Both you and your sexual partner must understand the importance of not becoming pregnant during or within at least three years after stopping Taro-Acitretin.

### Severe birth defects commonly associated with Taro-Acitretin use include:

- External ear abnormalities (e.g., low-set ears)
- Eye abnormalities (e.g., wide-set eyes)
- High palate
- Absence of fingers and/or toes
- Enlarged head, small chin
- Malformation of bones (hip, ankle, forearm, skull)
- Defects that affect the brain, heart, lymph glands, and nervous system



**Before starting Taro-Acitretin treatment, women must sign the "Informed Consent Form for Patients" that explains the risks of severe birth defects associated with taking the drug. It is extremely important to understand all of the information on the consent form and to ask the doctor any questions you might have.**



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## What Everyone Needs to Know Before Taking Taro-Acitretin

**SERIOUS SIDE EFFECTS:** If you experience any of the following side effects/symptoms while taking Taro-Acitretin, stop taking the drug and seek emergency treatment immediately:

- **Signs of a potential heart attack or stroke** such as chest pain, shortness of breath, dizziness, nausea, trouble speaking, weakness
- **Signs of a potential blood clot** such as swelling of a leg, ankle, foot, or arm
- **Symptoms of depression or worsening depression.** Some people taking Taro-Acitretin may develop mental health issues that include depressed mood, worsening depression, feelings of aggression, or thoughts of suicide.  
**If you have worsening depression, thoughts of suicide, or thoughts of self-harm, seek emergency treatment immediately.**
- **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

**ADDITIONAL SERIOUS SIDE EFFECTS:** If you experience any of the following side effects/symptoms while taking Taro-Acitretin, stop taking the drug and call your doctor immediately:

- **Symptoms that may be signs of increased pressure in the brain that can lead to blindness or even death** such as abdominal pain, bad headaches, diarrhea, nausea, vomiting, blurred vision.
- **Reduced night vision (known as night blindness) or other visual problems.** Problems with seeing can begin suddenly, so you should always be very careful when driving at night. STOP DRIVING IMMEDIATELY, and contact your doctor if you develop any vision problems or eye pain.
- **Symptoms of serious liver damage** that may include yellowing of your skin or whites of your eyes (jaundice), dark urine, flu-like symptoms, nausea and vomiting, or loss of appetite
- **Severe skin reactions** that may include redness, rash, and peeling of the skin
- **Signs of abnormal changes to the bones and muscles** such as aches or pain in bones or joints, or difficulty moving
- **Rectal bleeding**



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**COMMON SIDE EFFECTS:** Contact your doctor to see if you need to change anything about the way you take Taro-Acitretin or if you develop any of the following side effects or any unusual reactions. These side effects usually get better after you reduce the dose of Taro-Acitretin or the drug is stopped.

**Some 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.

**CONTACT YOUR DOCTOR IF ANY OF THESE COMMON SYMPTOMS BECOME BOTHERSOME:**

- Nosebleeds
- Ear problems (e.g., pain, wax build-up, or buzzing in the ear)
- Inflammation along the edge of the eyelid (blepharitis) or infection of the membrane lining the eyelids (conjunctivitis)
- Hair loss or abnormal hair texture
- Bleeding or inflammation of the gums, or inflammation of the mucous lining of the mouth
- Infections, including skin around the fingernail
- Skin problems such as cold sweats; excessive sweating; sensitivity to sunlight; inflamed, ulcerated, oily, or cracked skin

**Increase in blood cholesterol levels:** Taro-Acitretin may cause your blood cholesterol or triglyceride (lipids) levels to rise. Although this is not usually a serious problem, the doctor will order regular blood tests just in case the situation at any time requires medical attention.

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



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## A Checklist for Pregnancy Prevention While Taking Taro-Acitretin

- ❑ Two pregnancy tests that both show negative results should be done in a licensed laboratory before starting Taro-Acitretin. The first test should be completed at the 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.
- ❑ Talk with your doctor about two effective and complementary methods of birth control before starting to take Taro-Acitretin capsules (see p. 2).
- ❑ Two different types of birth control should be used at the same time for at least one month before and during treatment with Taro-Acitretin and for at least three years after you stop the medication. The birth control methods should be chosen by you and your doctor, and at least one of the methods must be a primary method (see birth control methods on p. 2).
- ❑ Ask your doctor or pharmacist if you are not sure what type of birth control pills you are using.
- ❑ You must use two reliable birth control methods even if you have a history of infertility or are not sexually active (unless you have had a hysterectomy or are at least one year past menopause), or you must abstain completely from sexual intercourse. Talk about this with your doctor.
- ❑ You should not start taking Taro-Acitretin until the second or third day of your next menstrual period 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.
- ❑ You must have pregnancy tests at 28-day intervals while taking Taro-Acitretin and at least every one to three months for at least three years after stopping the medication.
- ❑ Read the "General Medication Guide for Patients" and this Preventing Pregnancy and Precautions Guide, and ensure you completely understand the information. If you have any questions at all, ask your doctor or pharmacist.



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## Safety Information about Taro-Acitretin and Pregnancy: A Summary

### PREGNANCY PLANNING AND SAFETY CHART

|                             | 2 FORMS OF<br>BIRTH CONTROL | 2 NEGATIVE<br>PREGNANCY TESTS | ONGOING<br>PREGNANCY TESTS* | NO<br>ALCOHOL | NO BLOOD<br>DONATION |
|-----------------------------|-----------------------------|-------------------------------|-----------------------------|---------------|----------------------|
| 1 MONTH BEFORE<br>TREATMENT | ✓                           |                               | ✓                           |               |                      |
| BEFORE<br>TREATMENT         | ✓                           | ✓                             | ✓                           |               |                      |
| DURING<br>TREATMENT         | ✓                           |                               | ✓                           | ✓             | ✓                    |
| 2 MONTHS AFTER<br>TREATMENT | ✓                           |                               | ✓                           | ✓             | ✓                    |
| 3 YEARS AFTER<br>TREATMENT  | ✓                           |                               | ✓                           |               | ✓                    |

\*Pregnancy tests each month before receiving prescription, at 28-day intervals during treatment, and every 1-3 months for 3 years after stopping treatment (all must be negative)



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**Stop taking Taro-Acitretin and contact your doctor immediately under the following circumstances:**

- **You become pregnant while taking Taro-Acitretin or during the three years after treatment has stopped.**
- **You miss your period while taking Taro-Acitretin or during the three years after treatment has stopped.**
- **Your period is shorter or longer than usual or is of abnormal intensity compared to usual.**

Important safety information about Taro-Acitretin and the Pregnancy Prevention Program is available from [Taro-acitretin.ca](http://Taro-acitretin.ca).

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

## Frequently Asked Questions

**What should I do if my birth control fails while taking Taro-Acitretin or within a three-year period after stopping the medication?**

If either of your two birth control methods fail while taking Taro-Acitretin or within the three-year period after stopping the medication, you should contact your doctor or pharmacist about options for emergency contraception as soon as possible.

In order to find out where you can get emergency contraception in your area, call your pharmacist or doctor, or to obtain confidential birth control counselling, you may contact Action Canada for Sexual Health & Rights 24-hour Canada-wide Access line at 1-888-642-2725.

**Is there a risk for severe birth defects if only the male partner is being treated with Taro-Acitretin?**

Studies indicate that there is minimal, if any, risk to an unborn child that has been fathered by a man using Taro-Acitretin, as the level of drug found in semen and seminal fluid is very low. However, males using Taro-Acitretin should be reminded to never share their medication with anyone.

**How long should birth control be used?**

Two forms of birth control (primary and secondary – see p. 2) should be used for one month before starting Taro-Acitretin, throughout the entire Taro-Acitretin treatment period, and for at least three years after stopping the medication. If at any time during this period you think you have had unprotected sex, or your birth control method has failed, be sure to contact your doctor to discuss your options.