INFORMED CONSENT FORM FOR PATIENTS

TARO-Acitretin

PREGNANCY PREVENTION PROGRAM

TARO

TARO-Acitretin

You must not sign this document unless you understand and will comply with all of the information/ instructions that are listed on this document that apply to you, and have understood all of the information that your doctor has discussed with you about Taro-Acitretin.

Section 1: For male and female patients

After discussion with my doctor about Taro-Acitretin, I understand all of the following:

✔ Taro-Acitretin is used to treat severe psoriasis and other similar skin disorders. My doctor has informed me of different options for treating the particular skin problem that I have.

✔ I understand that Taro-Acitretin may cause serious side effects that could include:

- Severe birth defects in babies (deformed babies) born to women who have taken Taro-Acitretin in the month before pregnancy or during pregnancy or in women who become pregnant up to three years after stopping treatment with Taro-Acitretin.
- I further understand that the serious side effects of Taro-Acitretin can occur regardless of HOW LONG I have been taking the medication.

✔ I must keep all scheduled appointments with my doctor and fulfill all requests to have laboratory tests done.

✔ I must not share Taro-Acitretin with any other person, and I must return all unused Taro-Acitretin to a pharmacy after I am finished with my treatment.

✔ I must not drink alcohol or consume it in food or medicines while I am taking Taro-Acitretin and for at least two months after stopping the medication.

✔ I must not donate blood while taking Taro-Acitretin and for at least three years after stopping the medication.

✔ I acknowledge that both verbal and written information about the risks associated with taking Taro-Acitretin have been provided to me by my doctor.

Signature of Patient, Parent/Guardian: _____

Address: _____ **Telephone #:** _____

Physician Name: _____ **Date:** _____

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Section 2: For female patients of childbearing potential only

I have read the "General Medication Guide for Patients" and the "Preventing Pregnancy and Precautions Guide for Patients" and have completed the "Patient Knowledge Test – Understanding the Importance of Preventing Pregnancy" document. In addition, I have discussed risks associated with Taro-Acitretin treatment with my doctor and have discussed other treatment options available for my condition.

I understand all of the following regarding risks associated with Taro-Acitretin treatment:

- ❑ Treatment with Taro-Acitretin is associated with a high risk of severely deformed babies if taken at any time starting from one month before pregnancy until at least three years after the last dose of Taro-Acitretin has been taken.
- ❑ I must not become pregnant the month before planning to take Taro-Acitretin, during Taro-Acitretin treatment, **and for at least three years after taking my last dose of Taro-Acitretin.**
- ❑ I must verify that I am not pregnant during the times listed above (unless I have had a hysterectomy or am at least one year past menopause) by having pregnancy tests conducted by a licensed laboratory (even if I think I cannot become pregnant, I do not have regular menstrual periods, or if I am currently sexually inactive) in the following manner:
    - A negative pregnancy test when first considering Taro-Acitretin treatment with my doctor
    - A second negative pregnancy test not more than three days before starting Taro-Acitretin treatment. I must start treatment on the second or third day of my next menstrual period unless I am using treatment that prevents me from having periods (e.g., extended hormonal contraception, progesterone intrauterine device).
    - A pregnancy test every 28 days until my last dose of Taro-Acitretin. Before receiving another prescription for Taro-Acitretin, I must have a negative pregnancy test not older than three days from a licensed laboratory.
    - A pregnancy test every one to three months from my last dose of Taro-Acitretin for at least another three years
    - If any pregnancy test is positive, I must stop taking Taro-Acitretin and contact my doctor as soon as possible to discuss options.
- ❑ Because any birth control may fail, **I must use two different and complementary methods of birth control** at the same time starting at least one month before starting Taro-Acitretin, during Taro-Acitretin treatment, **and for at least three years after stopping treatment with Taro-Acitretin**. This applies to any course of Taro-Acitretin, regardless of how long I have taken the drug.
    - Two different and complementary methods of birth control refer to one primary method and one secondary method of birth control.
        - **Primary methods of birth control** include birth control pills, tubal ligation (tubes tied), vasectomy of male partner, topical/insertable/injectable hormonal birth control products and intrauterine devices (IUDs).
        - **Secondary methods of birth control** include latex condoms, diaphragms, and cervical caps. Each of these methods must be used with spermicidal cream or jelly.

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- ❑ Low-dose progesterone pills (mini-pills) are not considered to be a reliable method of birth control.
- ❑ I must not breastfeed while taking Taro-Acitretin and for three years after my last dose of the drug.
- ❑ I have spoken with my doctor about all other prescription and nonprescription (over-the-counter) drugs and herbal remedies that I am taking to assess whether or not they may interfere with birth control effectiveness.
    - Certain herbal remedies (e.g., St. John's wort) may reduce the effectiveness of hormonal birth control methods.
- ❑ I will immediately stop taking Taro-Acitretin and call my doctor as soon as possible under the following circumstances:
    - I become pregnant while being treated with Taro-Acitretin or up to three years after stopping treatment.
    - I stop my birth control, I feel that my birth control may have failed in any way, or I have unprotected sex at any time.
    - I miss my normal menstrual period or my menstrual period is abnormally short or long.
- ❑ If I become pregnant, I will stop taking Taro-Acitretin and speak to my doctor about options, including whether or not I wish to continue with the pregnancy.

Signature of Patient, Parent/Guardian: _____

Address: _____ **Telephone #:** _____

Physician Name: _____ **Date:** _____

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