



# PRESCRIBING CHECKLIST

**TARO-Acitretn**

PREGNANCY PREVENTION PROGRAM





# TARO-Acitretin

Patient Name: \_\_\_\_\_ Date: \_\_\_\_\_

Physician Name: \_\_\_\_\_

The "Prescribing Checklist" has been developed in order to help physicians determine the suitability and eligibility of female patients for receiving Taro-Acitretin treatment.

Unless the treating physician is satisfied that all of the criteria outlined below have been met, treatment with Taro-Acitretin is contraindicated in women of childbearing potential.

It is recommended that this document, along with the patient's signed informed consent, be kept in the patient's file in case it needs to be referred to in the future.

Taro-Acitretin (acitretin) is contraindicated in pregnancy. Taro-Acitretin is highly teratogenic and must not be used by females who are pregnant or intend to become pregnant. Taro-Acitretin is also contraindicated in females of childbearing potential unless strict contraception is practised four weeks before start of treatment, during treatment, and for at least three years after treatment cessation.

| <b><u>Taro-Acitretin MUST NOT be prescribed if the answer to any of the following questions is NO or the informed consent document has not been signed.</u></b>                                                                                                                                                                                                                          | <b>YES</b> | <b>NO</b> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------|
| 1. <b>Reliable and able to understand instructions:</b> The patient is deemed reliable and able to understand and follow all instructions relating to the safety of Taro-Acitretin use.                                                                                                                                                                                                  |            |           |
| 2. <b>Understands risk of fetal malformations:</b> The patient has received and read written documentation and has been verbally counselled about the high risk of severe fetal malformations associated with taking Taro-Acitretin four weeks before or during pregnancy, and that the risk remains for three years after completing treatment.                                         |            |           |
| 3. <b>Understands and able to use effective birth control:</b> The patient understands the importance of using two different types of effective and complementary birth control and is able to comply with instructions for correct use starting one month before start of treatment, during treatment, and continuing for at least three years after stopping Taro-Acitretin treatment. |            |           |
| 4. <b>Understands consequences of contraception failure:</b> The patient understands that failure of contraception could result in pregnancy and a baby that is born with severe birth defects. Patient has been counselled that if she suspects any contraception failure while taking Taro-Acitretin, she should immediately discuss options with her physician.                       |            |           |



# TARO-Acitretin

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | YES | NO |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|----|
| 5. <b>Able to comply with pregnancy test requirements:</b> The patient has had two negative pregnancy test results from a licensed laboratory. The first test was completed at time of initial assessment, and the second was completed no more than three days before starting Taro-Acitretin treatment. The patient understands that while taking Taro-Acitretin, pregnancy tests from a licensed laboratory conducted every 28 days are required and that a negative pregnancy test conducted not more than three days earlier is required before a prescription renewal is granted. The patient understands that regular pregnancy tests from a licensed laboratory conducted every one to three months are required for at least three years after finishing therapy. |     |    |
| 6. <b>Understands therapy start date requirement:</b> The patient has been counselled and understands to start her first dose of Taro-Acitretin on the second or third day of the next menstrual period, unless the patient is using treatment that prevents her from having periods (e.g., extended hormonal contraception, progesterone intrauterine device).                                                                                                                                                                                                                                                                                                                                                                                                            |     |    |
| 7. <b>The patient is not nursing a baby.</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |     |    |
| 8. <b>Understands requirement for abstaining from alcohol:</b> The patient understands that she must not drink alcohol or consume it in food or medicines while taking Taro-Acitretin and for at least two months after stopping treatment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |     |    |
| 9. <b>Understands blood donation restriction:</b> The patient understands that she must not donate blood while taking Taro-Acitretin and for three years after taking the last dose.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |     |    |
| 10. <b>The patient understands that if she becomes pregnant at any time during therapy, she must stop taking Taro-Acitretin and contact her doctor immediately.</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |     |    |

**Before starting treatment with Taro-Acitretin the treating physician must be satisfied that ALL of the criteria listed above have been met by the patient.**

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