Note to physician: Please retain a copy in the patient's file.

Name of patient:_____ Date:_____

Name of physician: _____

PREGNANCY PREVENTION CHECKLIST

MINT-ACITRETIN must not be used by females who are pregnant, planning to become pregnant or may become pregnant while undergoing treatment or within at least 3 years of completing treatment.

MINT-ACITRETIN (acitretin capsules) is a medication (retinoid) associated with severe human fetal abnormalities. The checklist is supplied by Mint Pharmaceuticals to assist physicians in determining patient suitability when treatment with MINT-ACITRETIN is being considered for a female patient. It is recommended that this checklist be retained in the patient's file for convenient reference.

MINT-ACITRETIN is contraindicated in women of childbearing potential unless, after deciding that the patient is a MINT-ACITRETIN candidate, you, the physician, are satisfied that they meet the criteria listed below. Please complete the following checklist:

If the answer to any of the following is NO, DO NOT prescribe MINT-ACITRETIN	**YES**	**NO**
1 The patient is reliable in understanding and following all instructions.		
2 The patient is capable of complying with effective contraceptive measures (complete abstinence or simultaneous use of two effective and complementary forms of birth control) starting 1 month before, during, and for **at least 3 years** after stopping MINT-ACITRETIN therapy.		
3 The patient has received **oral and written warnings** of the high risk of severe fetal malformations if MINT-ACITRETIN is taken during pregnancy as well as 3 years after stopping.		
4 The patient has been counselled on the risk of possible contraception failure and its consequences (severe birth defects).		
5 The patient has had two negative serum or urine pregnancy tests (from a licensed laboratory with a minimum sensitivity of 25 mIU/mL) before starting with MINT-ACITRETIN therapy: The first test (with a negative result) was done at the time of the initial assessment when the patient was qualified for MINT-ACITRETIN therapy; the second (confirmatory) test (with a negative result) was performed within 3 days prior to the first dose.		
6 The patient has been counselled to wait to start taking the first dose of MINT-ACITRETIN until the 2nd or 3rd day of her next menstrual period.		
7 The patient is not a nursing mother.		
8 The patient understands the need for rigorous follow-up on a monthly basis and will schedule monthly appointments with you for monitoring and for a monthly (28– day intervals) pregnancy test conducted by a licensed laboratory. A negative pregnancy test not older than 3 days is required before a prescription renewal is provided.		
9 The patient understands that after stopping therapy and **for at least 3 years** after the last dose was taken, pregnancy tests, from a licensed laboratory, are to be performed at 1-3 monthly intervals.		
10 If the patient becomes pregnant, she understands that she must stop taking MINT-ACITRETIN immediately and notify her physician.		
11 The patient will sign the consent to treatment form.		

Because of the extremely high risk of severe birth defects, the patient should only be placed on MINT-ACITRETIN therapy once you are satisfied that the patient has met the above criteria. Therapy should begin on the second or third day of the patient's next menstrual period after confirmation of a negative pregnancy test conducted by a licensed laboratory not older than 3 days before initiating therapy.

Important safety information about MINT-ACITRETIN and the MINT-ACITRETIN Pregnancy Prevention Program is available from:

- Online: www.mint-acitretin.com or • To speak to someone or to report an Adverse Reaction, please contact the Mint Pharmaceuticals MEDICAL SAFETY INFORMATION LINE at (toll-free) 1-877-398-9696