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

Name of patient: _____ Date: _____

Name of physician: _____

Pregnancy Prevention Checklist

ACCUTANE™ ROCHE® (isotretinoin) must not be used by females who are pregnant or who may become pregnant while undergoing treatment.

ACCUTANE is a severe teratogenic agent that is associated with major human fetal abnormalities. This checklist is supplied by Hoffmann-La Roche Limited to assist physicians in determining patient suitability when treatment with ACCUTANE is being considered for the female patient. It is recommended that this checklist be retained in the patient's file for convenient reference.

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

If any **NO** box is checked, **DO NOT** prescribe ACCUTANE	**YES**	**NO**
1. The patient is reliable in understanding and carrying out all instructions.		
2. The patient is capable of complying with effective contraceptive measures (complete abstinence or simultaneous use of two effective forms of birth control) starting one month before, during, and one month after ACCUTANE therapy.		
3. The patient has received **oral and written warnings** of the hazards of taking ACCUTANE during pregnancy.		
4. The patient has been counselled on the risk of possible contraception failure and its consequences.		
5. The patient has had two negative pregnancy tests before starting ACCUTANE therapy with the first pregnancy test conducted at initial assessment when the patient is qualified for ACCUTANE therapy by the physician. The patient has had a second serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL with a negative result, performed in a licensed laboratory, within 11 days prior to initiating therapy. The patient has had two or three days of the next normal menstrual period before ACCUTANE therapy is initiated.		
6. The patient is not a nursing mother.		
7. The patient understands the need for rigorous follow-up on a monthly basis and will schedule monthly appointments with you for monitoring.		
8. If the patient becomes pregnant, she understands that she must stop taking ACCUTANE immediately and call for an urgent appointment to discuss options concerning continuing the pregnancy.		
9. The patient will sign the consent to treatment form.		

If the answer to any of these questions is NO, then the patient must not receive ACCUTANE.

Because of the extremely high risk of birth defects, the patient should only be placed on ACCUTANE once you are satisfied that she has met the above criteria. Therapy should only begin on the second or third day of the patient's next normal menstrual period after confirmation of a negative pregnancy test taken in the preceding two weeks.

Avoid Pregnancy **Birth Control Counselling Hotline** **1-877-333-2263**

For full prescribing information, please consult the ACCUTANE™ ROCHE® Product Monograph.

To report an Adverse Event, please contact:
Roche Medical Information Department (toll-free): 1-888-762-4388
or Medical Information mailbox: mississauga.canada_medinfo@roche.com

If you require this information in an accessible format, please contact Roche at 1-800-561-1759.

This material was developed by Hoffmann-La Roche, as part of the risk minimization plan for ACCUTANE. This material is not intended for promotional use.

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