Clarus®
Isotretinoin Capsules, USP

VIATRIS

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

Name of patient: _____ **Date:** _____

Name of physician: _____

PREGNANCY PREVENTION CHECKLIST

CLARUS® must not be used by females who are pregnant or who may become pregnant while undergoing treatment.

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

CLARUS® is contraindicated in women of childbearing potential unless, after deciding the patient is a CLARUS® 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 CLARUS®	**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 CLARUS® therapy.	☐	☐
3. The patient has received **oral and written warnings** of the hazards of taking CLARUS® 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 CLARUS® therapy, with the first pregnancy test conducted at initial assessment when the patient is qualified for CLARUS® 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 CLARUS® therapy is initiated.	☐	☐
6. The patient is not a nursing mother.	☐	☐
7. The patient will schedule monthly appointments with you for monitoring.	☐	☐
8. If the patient becomes pregnant, she understands that she must stop taking CLARUS® 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 CLARUS®.

Because of the extremely high risk of birth defects, the patient should only be placed on CLARUS® 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, following confirmation of negative pregnancy test results taken in the preceding 11 days.

Avoid Pregnancy – Birth Control Counselling Hotline 1-877-776-7711

PRESCRIBER'S COPY (white) PATIENT'S COPY (yellow)