ABSORICA LD® (isotretinoin) Clinical Awareness Resource and Education C-A-R-E™ Program: Pregnancy Prevention Checklist

DISCLAMER: This material was developed by Sun Pharmaceutical, as part of the risk minimization plan for ABSORICA LD. This material is not intended for promotional use.

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

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

Name of physician: _____

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

ABSORICA LD 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 ABSORICA LD is being considered for a patient. It is recommended that this checklist be retained in the patient's file for convenient reference.

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

	If any "NO" box is checked,* DO NOT prescribe ABSORICA LD.	YES	NO
1	The patient has severe nodular and/or inflammatory acne, acne conglobata, or recalcitrant acne that has not responded to standard therapy, including systemic antibiotics.	☐	☐
2	The patient is reliable in understanding and carrying out all instructions.	☐	☐
3	The patient is capable of complying with effective contraceptive measures (complete abstinence or simultaneous use of 2 effective forms of birth control and at least one is a primary method) starting 1 month before, during, and 1 month after ABSORICA LD therapy.	☐	☐
4	The patient has received **oral and written warnings** of the hazards for pregnancy, breastfeeding, and donating blood or blood products during and for at least 1 month after stopping treatment with ABSORICA LD.	☐	☐
5	The patient has been counselled on the risk of possible contraception failure and the consequences related to severe birth defects in fetuses exposed to ABSORICA LD.	☐	☐
6	The patient has had 2 negative pregnancy tests performed in a licensed laboratory before starting ABSORICA LD therapy, with the first pregnancy test conducted at initial assessment when the patient is qualified for ABSORICA LD 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 within 11 days prior to initiating therapy. The patient has had 2 or 3 days of the next normal menstrual period before ABSORICA LD therapy is initiated.	☐	☐
7	The patient is not a nursing mother.	☐	☐
8	The patient understands that she must schedule monthly appointments with you for monitoring and to receive subsequent prescriptions.	☐	☐
9	If the patient becomes pregnant, she understands that she must stop taking ABSORICA LD immediately and call for an urgent appointment to discuss options concerning continuing pregnancy.	☐	☐
10	In the event of relapse treatment, the patient must also use the same uninterrupted and effective contraceptive measures 1 month prior to, during, and for 1 month after the use of ABSORICA LD.	☐	☐
11	The patient has agreed to sign the Patient Informed Consent Form.	☐	☐

If the answer to any of these questions is "NO,"* then the patient must not receive ABSORICA LD.

Because of the extremely high risk of birth defects, the patient should only be placed on ABSORICA LD once you are satisfied that he/she has met the criteria above. For women, 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 11 days.

*For male patients, write n/a for sections 6, 8, and 9.

For information about birth control or for confidential counselling, contact Sun Pharma Canada Customer Service at Med.InfoCanada@sunpharma.com, by phone at 1-833-388-0532, or visit the ABSORICA LD website at www.ABSORICALD.ca.

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