ABSORICA LD® (isotretinoin) Clinical Awareness Resource and Education C-A-R-E[™] Program: Psychiatric Screening Checklist

DISCLAIMER: 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. **Patient Name:** Date: Physician Name: Psychiatric evaluation should be part of the monthly assessment during ABSORICA LD therapy. All patients must sign the Patient Informed Consent, which is available on the ABSORICA LD website at www.ABSORICALD.ca or by calling the toll-free number at 1-833-388-0532. Depression and potential for suicide have been reported during and after therapy. In some of these patients, depression has subsided with discontinuation of therapy and recurred when isotretinoin therapy was reintroduced. Emotional instability has been reported with isotretinoin. If symptoms of depression develop or worsen during treatment, the drug should be discontinued promptly and the patient referred to appropriate psychiatric treatment. The full Product Monograph and the Patient Medication Information can be found on the ABSORICA LD website at www.ABSORICALD.ca or by calling the toll-free number at 1-833-388-0532. Prior to prescribing ABSORICA LD, a careful assessment of the patient's mental state should be made, including whether or not the patient has a personal or family history of previous psychiatric illness. It may be useful for physicians to screen patients prior to prescribing ABSORICA LD and/or monitor patients during ABSORICA LD therapy using available tools. The Patient Health Questionnaire (PHQ-9) is provided in this package as an example of a tool. Please note that this questionnaire has not been validated specifically for use in patients taking isotretinoin in products for treatment of acne. Patient input from the PHQ-9 is meant to provide assistance in evaluating your patient's mental health status. The results of the questionnaire, along with other clinical information, may be used to modify treatment or make further referrals for psychiatric consult upon clinical discretion on a case-by-case basis. The management of depression detected through screening is at the discretion of the physician. Other questionnaires/tools may also be available and appropriate based on the physician's professional judgment. More than Nearly Not at all Several days Patient Health Questionnaire (PHQ-9)* half the days every day Over the last 2 weeks, how often have you been bothered by any (0 points) (3 points) 1 (1 point) (2 points) of the following problems? а Little interest or pleasure in doing things h Feeling down, depressed, or hopeless Trouble falling/staying asleep, sleeping too much С Feeling tired or having little energy d е Poor appetite or overeating Feeling bad about yourself or that you are a failure or have let yourself or your family down Trouble concentrating on things, such as reading the newspaper or watching Moving or speaking so slowly that other people could have noticed. Or the opposite, being so fidgety or restless that you have been moving around a lot h Thoughts that you would be better off dead or hurting yourself in some way Not difficult Extremely Very difficult difficult difficult at all If you checked off any problem on this questionnaire so far, how difficult have 2 these problems made it for you to do your work, take care of things at home, or get along with other people? PHQ-9 Scoring and Interpretation Guide (For physician use only) Scoring: Count the number (#) of boxes checked in section 1. Multiply that number Interpreting PHQ-9 Scores Score by the value indicated below; then add the subtotals to produce a total score. The possible range is 0-27. Minimal depression 0-4 Use the table on the right to interpret the PHQ-9 score. Mild depression 5-9 (#)____x 0 = __ Not at all Moderate depression 10-14 (#) ____x 1 = _ Several days ___x2=_ Moderately severe depression 15-19 More than half the days ___x3=_ Severe depression 20-27 Nearly every day

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