

NOTE TO PHYSICIAN: PLEASE RETAIN A COPY IN THE PATIENT'S FILE
This material is provided by CHEPLAPHARM, as part of the risk minimization plan for ACCUTANE™ (isotretinoin). This material is not intended for promotional use.

Name of Patient: _____ Date: _____

Name of Physician: _____

PSYCHIATRIC ASSESSMENT CHECKLIST

Some patients treated with ACCUTANE have become depressed and some attempted or committed suicide. Although a causal relationship has not been established, it is prudent to screen and monitor all patients for signs of depression prior to start of treatment and periodically during therapy.

The following information is contained in the Product Monograph for ACCUTANE:

Serious Warnings and Precautions

Psychiatric: Some patients treated with ACCUTANE have become depressed and some attempted or committed suicide. Although a causal relationship has not been established, all patients should be screened and monitored for signs of depression before and during therapy (see WARNINGS AND PRECAUTIONS, Monitoring and Laboratory Tests). Physicians should determine whether the patient may be depressed or has a history of depression including a family history of major depression before starting therapy with ACCUTANE. If symptoms of depression develop or worsen during treatment with ACCUTANE, the drug should be discontinued promptly and the patient referred for appropriate psychiatric treatment as necessary. However, discontinuation of ACCUTANE may not alleviate symptoms and therefore further psychiatric or psychological evaluation may be necessary.

Adverse Reactions

"Psychiatric Disorders: Depression, psychotic symptoms and, rarely, suicide attempts, suicide, and aggressive and/or violent behaviours (see WARNINGS AND PRECAUTIONS: Psychiatric). Depression has been reported during and after therapy. In some of these patients, depression has subsided with discontinuation of therapy and recurred when ACCUTANE therapy was reintroduced. Emotional instability has been reported with ACCUTANE."

For complete information please consult the Product Monograph at www.AcneandU.ca. The Patient Medication Information can be downloaded from Health Canada website (<http://hc-sc.gc.ca/index-eng.php>) for distribution to patient at the point of care.

All patients must sign the informed consent form prior to initiating therapy. This form is available via the www.acneandu.ca website or by calling 1-888-XEDITON (933-4866).

It may be useful for physicians to screen patients prior to prescribing ACCUTANE and/or monitoring patients whilst on their ACCUTANE therapy using available tools. Example included in this package is the Patient Health Questionnaire-9 (PHQ-9). Other checklists may also be available and appropriate in the physician's professional judgment.

Specific management of depression detected through screening is at the discretion of the physician.

The PHQ-9 (supplied with this checklist) is a self-assessment questionnaire to be completed by the patient for review by the physician. *Please be advised that this questionnaire has not been validated for use in patients taking isotretinoin products for treatment of acne.*

The patient input from PHQ-9 below is meant to provide guidance in assessing your patient's mental health status. This information, along with other clinical information, may be used to modify treatment or make further referrals to a psychiatric consult, upon clinical discretion on a case-by-case basis. A careful assessment of the patient's mental state should be made, including whether or not they have a personal or family history of psychiatric illness.

Patient Health Questionnaire-9 (PHQ-9)* Nine-Symptom Checklist

Name: _____ Date: _____

Over the <i>last 2 weeks</i> , how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. 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 more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

(For office coding: Total Score _____ = _____ + _____ + _____)

If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

☐ Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult

Patient Health Questionnaire-9 (PHQ-9)* Scores

Name: _____ Date: _____

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- Specific management of depression detected through screening is at the discretion of the physician.

PHQ-9 Score	Depression Severity
1 – 4	None
5 – 9	Mild
10 – 14	Moderate
15 – 19	Moderately Severe
20 – 27	Severe

*Reference: Kroenke K, Spitzer RL. The PHQ-9: a new depression diagnostic and severity measure. *Psychiatric Annals* 2002;32:509-521.

You can report any suspected side effects associated with the use of health products to Xediton by contacting drugsafety@xediton.com or calling 1-888-XEDITON (933-4866); or to Health Canada by visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mpps/medeff/report-declaration/index-eng.php>) or calling toll-free at 1-866-234-2345.

For more information, please call the birth control counselling line at 1-888-XEDITON (933-4866)

If you require this information in an accessible format, please contact 1-888-XEDITON (933-4866).

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