

Apo-Clozapine Risk Management Program

PATIENT REGISTRATION

Phone: **1-877-276-2569**
 Fax: **1-866-836-6778**
 Website: **www.apoclozapine.com**

APO-CLOZAPINE ASSIGNED PIN:

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The Physician is responsible for registering the Patient in the Apo-Clozapine Risk Management Program. Please check one:

New Patient to Apo-Clozapine Patient Restart Modify currently registered Apo-Clozapine Patient Discontinuation
 PLEASE NOTE: TO COMPLETELY PROCESS NEW PATIENTS AND RESTARTS HEMATOLOGICAL RESULTS WITHIN THE LAST 30 DAYS ARE REQUIRED.

1 PATIENT REGISTRATION

Initials: Date of birth: / /

Sex: M F

Ethnicity: Caucasian Asian
 Black Other (Specify) _____

Status: Inpatient Outpatient

Health Card #: _____ / _____

Monitoring Frequency: Weekly Biweekly Every Four Weeks

Disposition (If patient is discontinuing Apo-Clozapine):
 Apo-Clozapine stop date : / /

Reason for discontinuation: PLEASE PRINT _____

Name: PLEASE PRINT _____

Title: PLEASE PRINT _____ Signature: _____

2 PATIENT'S TREATMENT RESOURCE TEAM - PHARMACIST REGISTRATION

If Pharmacy previously registered, please indicate Pharmacy PIN, and sign:

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Pharmacist Name: _____

Pharmacist License #:

Pharmacy Name: _____

Address: _____

Prov: Postal Code:

City: _____

Tel: - - Ext: _____

Fax: - -

Email: _____

If Website Login is requested: New User View only access Write and View access

I confirm that all dispensing pharmacists at this location will only dispense APO-CLOZAPINE at the specified frequency upon confirmation that the patient has had his/her blood drawn for a Complete Blood Count and Differential for the current period. If applicable, I also confirm responsibility for actions undertaken by the website login.

Date: / / Pharmacist's Signature: _____

3 PATIENT'S TREATMENT RESOURCE TEAM - PHYSICIAN REGISTRATION

If Physician previously registered, please indicate Physician PIN, and sign:

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Physician Name: _____

Physician License #:

Facility Name: _____

Address: _____

Prov: Postal Code:

City: _____

Tel: - - Ext: _____

Fax: - -

Email: _____

Statement by treating Physician
I, the treating physician, will ensure that blood testing (white blood cell count and differential) for this patient (identified below) as required by the Apo-Clozapine Product Monograph is performed at the specified frequency. I understand that no pharmacy will dispense any brand of clozapine to my patient without my prior knowledge and permission regarding which brand is being dispensed. In this way I will be able to inform the laboratory to send my patient's results to the appropriate manufacturer's clozapine database (Apo- Clozapine Risk Management Program). I will not prescribe Apo-Clozapine until the non-rechallengeable status of this patient has been verified.
 I have informed the patient and he/she has not objected to the release of relevant safety information held within a clozapine database to any other clozapine database of an approved manufacturer of clozapine in Canada, if needed for the safe utilization of this medication and/or for the continuous monitoring of the patient. The information which may be released, includes the non-rechallengeable/ hematological status of the patient, white blood cell counts and absolute neutrophil counts, dates and other information as may be relevant to the safe treatment of the patient with clozapine.

By selecting this box, I authorize the laboratory to release to Apotex (1-866-836-6778) all hematological CBC and differential lab results for this patient.

Date: / /

Physician's Signature: _____

4 PATIENT'S TREATMENT RESOURCE TEAM - LABORATORY AND COORDINATOR REGISTRATION

If laboratory previously registered, please indicate lab PIN:

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Laboratory Name: _____

Tel: - - Ext: _____

Fax: - -

If Coordinator/Case Manager/Nurse Practitioner is previously registered, please indicate Coordinator's site PIN:

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Coordinator Name: _____

Office/Clinic Affiliated Institution/Ward: _____

Tel: - - Ext: _____

Fax: - -

If Website Login is requested: New User View only access Write and View access

Coordinator's signature: _____

DISCLOSURE

- (a) I have reviewed and understand the Apotex Clozapine product monograph.
- (b) I understand that death can occur as a result of agranulocytosis with the use of APO-CLOZAPINE, and that all patients on APO-CLOZAPINE must be enrolled in the APO-CLOZAPINE Risk Management Program to help reduce the risk of a non-rechallengeable patient reusing APO-CLOZAPINE. I understand that patients placed on the non-rechallengeable list have had previous unacceptable WBC counts, and/or ANC values, and/or Clozapine-induced-myocarditis as defined in the APO-CLOZAPINE product monograph.
- (c) I understand that the patient's rechallengeable status will be verified prior to the initiation of treatment for all patients that are new to treatment, or for patients with an unknown or interrupted history on Clozapine.
- (d) I, the Physician, will only prescribe APO-CLOZAPINE following the receipt of a PIN number from the APO-CLOZAPINE Risk Management Program.
- (e) I agree to notify the APO-CLOZAPINE Risk Management Program of any discontinued patients or interruptions in APO-CLOZAPINE therapy.
- (f) I, the Physician, will ensure that if the patient is female, she is not pregnant nor breastfeeding.
- (g) I, the Pharmacist, will only dispense APO-CLOZAPINE following the receipt of a PIN number from the APO-CLOZAPINE Risk Management Program.
- (h) I, the Physician agree to ensure that hematological testing is performed at the required frequency (as per the product monograph) and submit copies of all lab reports indicating WBC and ANC results to Apotex within 7 days.
- (i) I agree to submit the four required weekly lab reports containing WBC and ANC counts after a patient discontinues Clozapine therapy.
- (j) I understand that the APO-CLOZAPINE Risk Management Program will monitor compliance with reporting requirements and will notify the patient's physician and/or pharmacist of any discrepancies or overdue lab reports.
- (k) In the event of agranulocytosis, clozapine-induced-myocarditis, or any other serious event, I agree to fill out the required Serious Adverse Event form(s) and send this form(s) directly to Medical Information at Apotex Inc. within 48 hours.