AA-Clozapine Patient Care Network - PATIENT REGISTRATION

Phone: 1-877-276-2569 / Fax: 1-866-836-6778 / Website: www.aaspire.ca

1165 Creditstone Rd., Unit 1, Vaughan, Ontario L4K 4N7

19-AA054_AAC0350E1

AA-CLOZAPINE ASSIGNED PIN:

FOR OFFICE USE ONLY

The Prescriber is responsible for registering the Patient in the AA-Clozapine Patient Care Network. Please check one:

☐ New Patient to AA-Clozapine ☐ Patient Restart ☐ Modify treatment partner for currently registered AA-Clozapine Patient

Hospitalization Related to AA-Clozapine ☐ Y ☐ N (Applicable for Active Patients Only)

1 PATIENT REGISTRATION

Initials: ☐ ☐ ☐ (First Middle Last) Date of Birth: ____/____/____ (DD MMM YYYY)

Sex: ☐ M ☐ F ☐ Other: _____

Ethnicity: ☐ Caucasian ☐ Asian ☐ Black ☐ Other (specify): _____

Status: ☐ Inpatient ☐ Outpatient ☐ No interruption in treatment

Health Card #: _____

Monitoring Frequency: ☐ Weekly ☐ Biweekly ☐ Every Four Weeks

Baseline Draw Date: ____/____/____ (DD MMM YYYY) WBC: _____ x10^9/L ANC: _____ x10^9/L

***Note:** New Registrations/Restarts require a CBC with differentials dated within the last 4 weeks. WBC must be ≥ 3.5 x10^9 /L and ANC must be ≥ 2.0 x10^9 /L*

3 PATIENT'S TREATMENT RESOURCE TEAM - PRESCRIBER REGISTRATION

Prescriber Name: _____

Prescriber Type: ☐ Physician ☐ Pharmacist ☐ Nurse Practitioner

Prescriber License #: ☐☐☐☐☐☐☐☐

Facility Name: _____

Address: _____

City: _____ Prov: ☐☐ Postal Code: ☐☐☐☐☐☐

Tel: ☐☐☐-☐☐☐-☐☐☐☐ Ext: _____

Fax: ☐☐☐-☐☐☐-☐☐☐☐

Email: _____

Statement by Treating Prescriber

I, the treating physician, authorized nurse practitioner or authorized pharmacist* will ensure that blood testing (white blood cell count and differential) for this patient as required by the AA-Clozapine Product Monograph is performed at the specified frequency. I understand that no pharmacy will dispense any brand other than AA-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 (the **"AA-Clozapine Risk Management Program"**). I will not prescribe AA-Clozapine until the non-rechallengeable status of this patient has been verified. In addition, I understand that: (i) the AA-Clozapine Risk Management Program will only keep relevant patient information, such as white blood cell count and differential details, for each patient as required by the AA-Clozapine Product Monograph; and (ii) any other additional patient information that is collected during the course of this study will only be shared with a prescriber and/or will be deleted from the AA-Clozapine Risk Management Program. I understand that AASPIRE will not keep any information collected from the patient except for the patient data that is required in accordance with the AA-Clozapine Product Monograph. I have informed the patient about the type of patient information being collected, its intended use and the third parties that such information may be disclosed to, as set out herein. Furthermore, I confirm that the patient consents to such collection, use and disclosure. Lastly, I understand that relevant safety information held within a clozapine database may be released 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 this 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.

**In selected provinces, according to the College of Nurse, College of Pharmacy guidelines/regulations for applicable provinces*

Date: ____/____/____ (DD MMM YYYY)

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

Prescriber's Signature: _____

2 PATIENT'S TREATMENT RESOURCE TEAM - PHARMACIST REGISTRATION

Pharmacist Name: _____

Pharmacist License #: ☐☐☐☐☐☐☐☐

APA Designation: ☐ Y ☐ N

Pharmacy Name: _____

Address: _____

City: _____ Prov: ☐☐ Postal Code: ☐☐☐☐☐☐

Tel: ☐☐☐-☐☐☐-☐☐☐☐ Ext: _____

Fax: ☐☐☐-☐☐☐-☐☐☐☐

Email: _____

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

Date: ____/____/____ (DD MMM YYYY) Pharmacist's Signature: _____

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

Laboratory Name: _____

Address/City: _____

Tel: ☐☐☐-☐☐☐-☐☐☐☐ Ext: _____

Fax: ☐☐☐-☐☐☐-☐☐☐☐

Coordinator Name: _____

Site: _____

Address/City: _____

Tel: ☐☐☐-☐☐☐-☐☐☐☐ Ext: _____

Fax: ☐☐☐-☐☐☐-☐☐☐☐

PLEASE NOTE: Please ensure AA Pharma is placed on the Standing Order/Requisition form so that we receive copies of the CBC results for the patient.

DISCLOSURE

a) I have reviewed and understand the AA-CLOZAPINE product monograph when assistance is required from a hematologist for low WBC and ANC counts a request will be sent to the AA Clozapine Patient Care Network via phone/e-mail/fax.

b) I understand that death can occur as a result of agranulocytosis with the use of AA-CLOZAPINE, and that all patients on AA-CLOZAPINE must be enrolled in the AA-CLOZAPINE Patient Care Network to help reduce the risk of a nonrechallengeable patient reusing AA-CLOZAPINE. Iunderstand that patients placed on the nonrechallengeable list have had previous unacceptable WBC counts, and/or ANC values, and/or Clozapine induced myocarditis as defined in the AA-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 forpatients with an unknown or interrupted history on Clozapine.

(d) I, the Prescriber, will only prescribe AA-CLOZAPINE following the receipt of aPIN number from the AA-CLOZAPINE Patient Care Network.

(e) I agree to notify the AA-CLOZAPINE Patient Care Network of anydiscontinued patients or interruptions in AA-CLOZAPINE therapy.

(f) I, the Prescriber, will ensure that if the patient is female, she is not pregnantnor breastfeeding.

(g) I, the Pharmacist, will only dispense AA-CLOZAPINE following the receipt of aPIN number from the AA-CLOZAPINE Patient Care Network.

(h) I, the Prescriber agree to ensure that hematological testing is performed at therequired frequency (as per the product monograph) and submit copies of all lab reports indicating WBC and ANC results to AA Pharma within 7 days.

(i) I agree to submit the four required weekly lab reports containing WBC andANC counts after a patient discontinues Clozapine therapy.

(j) I understand that the AA-CLOZAPINE Patient Care Network 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, including any lack of drug effect and any clozapine related hospitalization I agree to fill out the required Serious Adverse Event form(s) and send this form(s) directly to AA-Clozapine Patient Care Network within 24 hours via fax to 18668366778 or report via phone to 18772762569.