
November 3, 2020

Re: PrCLOZARIL® (clozapine) – Monitoring during COVID-19, update on Health Canada Guidance

On March 20, 2020, and on July 20, 2020, CSAN® announced that Health Canada had issued interim recommendations that could be implemented by Health Care Professionals that were managing patients being treated with PrCLOZARIL®, and that such guidance would be subject to review in three months or sooner as appropriate.

We are now within what has been defined as the second wave of the COVID-19 pandemic and Health Canada has advised, their previous guidance for clozapine monitoring of neutrophil counts will remain in effect for another 90-days.

Health Canada has provided the following guidance to CSAN®.

- At the current time, testing paradigms appear to be reverting to their pre-pandemic status for some clozapine patients. Nevertheless, there does remain a great deal of uncertainty about future developments in the COVID-19 pandemic. **As such, Health Canada recommends that, if possible, patients should continue to have white blood cell (WBC) counts and absolute neutrophil counts (ANC) testing as per their regular schedule for hematologic monitoring. Health Care Professionals should continue to use their best clinical judgment in weighing the benefits and risks of continuing treatment in the absence of laboratory testing;**
- Health Care Professionals should also communicate with their patients regarding these judgments, including the risks associated with it, and begin the processes as appropriate to return to a normal testing schedule;
- Missing or delayed laboratory tests and the reasons should be properly documented and CSAN® should report these reasons to Health Canada on a monthly basis;
- These recommendations for blood testing will be reassessed in three months or sooner; and
- Ultimately, it is anticipated that blood-testing requirements will eventually return to their usual status, although there remains uncertainty related to potential prolongation of the COVID-19 pandemic.

While Health Canada provided guidance that allowed for laboratory testing forgiveness for clozapine if appropriate, it is impressive that to-date the vast majority of CSAN® patients were able to maintain their normal testing intervals.

Since March 2020, health care teams have developed and learned how to manage patients during this time of the COVID-19 epidemic, and new systems and technologies have contributed to this new understanding.

The CSAN® Program has launched CSAN® Pronto™, a point of care capillary testing program to help simplify access to routine WBC monitoring for CLOZARIL® patients. For more information please contact HLS Therapeutics.

The CSAN® program is proud to be part of your health care team for nearly 30 years, and we continue to be here to support you. Should you need assistance please contact your local CSAN® Nurse Educator, as noted below, or the CSAN® program at (800) 267-2726.

Region	Nurse Educator	Phone Number
Ontario West	Olga Kurylo	(416) 779-7158
Ontario East	Sue Swaine	(613) 720-1131
Ontario Ottawa	Sarah Marchand-Lacoursière	(514) 229-5776
Quebec West	Marie-France Sabourin	(514) 951-4703
Quebec East	Sophie Ferland	(418) 563-7938
Atlantic	Sophie Ferland	(418) 563-7938
West Coast	Moriah Tate	(780) 281-1332

The CSAN® Team and HLS Therapeutics would like to commend all Health Care Professionals for their dedicated efforts during this historical period.

Sincerely,



Jason A. Gross, Pharm.D.
Vice President, Scientific Affairs
HLS Therapeutics Inc.
www.hlstherapeutics.com

In accordance with the Therapeutic Products Directorate and the CLOZARIL® Product Monograph, CLOZARIL® is available only through a distribution system that ensures maintenance of a CLOZARIL®-specific national database. The switching of a patient from one brand of clozapine to another must not be done by a pharmacist unless he/she obtains a new, registry-specific patient registration form filled out by the prescribing physician.¹ For more information the product monograph may be accessed at www.Clozaril.ca.