
July 20, 2020

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

On March 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.

Today, the COVID-19 pandemic remains at the center of the news, as many provinces and health care systems are entering various phases of COVID-19 recovery.

Today Health Canada has provided the following updated guidance to CSAN.

- No emerging safety concerns have been identified for the period of mid-March to end of June 2020;
- 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 providers 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 test, the reason 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.

To help support patient care HLS Therapeutics has held a total of 28 webinars during this COVID-19 period, attended by over 900 participants, and many of you participated in these efforts.

As we begin the process of moving into the recovery phase of the COVID-19 Pandemic, the CSAN Team and HLS Therapeutics would like to commend all Health Care Professionals for their dedicated efforts during this historical period.

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

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.

MLR NS 20200705 E COM