

October 6, 2022

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

Dear Health Care Professionals,

With respect to the COVID – 19 Pandemic, Health Canada has requested that HLS Therapeutics Inc., notify Health Care Professionals of the following:

On March 20, 2020, Health Canada issued interim recommendations to be implemented by Health Care Providers who are managing patients being treated with **CLOZARIL®**. At the time, Health Canada had requested **HLS** to:

- 1) monitor compliance rates and associated adverse events occurrence; and
- 2) inform stakeholders that as an interim measure during the COVID-19 crisis, it would be reasonable for Health Care Providers to use their best medical judgement to allow continued dispensing of clozapine even if patients are late in getting or unable to get their blood tested.

As of September 23, 2022, Health Canada asked HLS Therapeutics Inc. to inform Health Care Professionals that Health Canada recognizes under extenuating circumstances related to the COVID-19 pandemic, challenges may still exist that hinder access to testing for some patients.

As previously communicated, Health Canada recommends that, if possible, patients continue to have white blood cell (WBC) counts and absolute neutrophil counts (ANC) testing as per their regular schedule for hematologic monitoring. However, if necessary, Health Care Providers 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 associated risks.

Health Canada’s assessment of the current situation is supportive of extending the current flexibility around hematological testing by an additional 12 months (until September 30, 2023). However, this recommendation is subject to change. Hematological testing requirements will continue to be reassessed by Health Canada with the progression of the COVID-19 pandemic. It is anticipated that blood testing requirements will eventually return to their usual pre-pandemic status. You will be updated regarding any future changes to the requirements.

The CSAN® program is proud to be part of your health care team for over 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 (800) 267-2726.

Region	Nurse Educator	Phone Number
Ontario West	Christopher Komel	(647) 244-0765
Ontario East	Sue Swaine	(613) 720-1131
Ontario Ottawa	Dorit Dayan	(514) 229-5776
Quebec West	Dorit Dayan	(514) 951-4703
Quebec East	Candice Rossi	(418) 563-7938
Atlantic Region	Candice Rossi	(418) 563-7938
West Coast	Moriah Tate	(780) 281-1332

Please note: the CSAN® Program is now using the **CSAN® Pronto®**, a point of care capillary testing program, to simplify access to routine hematological monitoring for CLOZARIL® patients. For more information, please contact CSAN® at 1-800-267-2726.

The CSAN® Team and HLS 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.² For more information the product monograph may be accessed at www.Clozaril.ca.

CLOZARIL, CSAN and CSAN Patient Care Portal + Design are all registered trademarks of Novartis AG. Pronto is a registered trademark of HLS Therapeutics Inc.

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References: ¹ Health Canada Correspondence to HLS Therapeutics Inc September 23, 2022 ²Health Canada. Press release, monitoring of patients taking clozapine. <http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2004/14249a-eng.php>, accessed November 27, 2017
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