
August 2, 2021

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

Dear Health Care Professionals;

Health Canada has requested that HLS Therapeutics Inc. notify Health Care Professionals of the following:

As of July 8, 2021, Health Canada has confirmed their previous guidance remains in effect and has requested that Health Care Professionals be made aware of clozapine toxicity that may be associated with infections and/or inflammation as noted:

Patient Monitoring

Health Canada recognizes that despite decreasing COVID-19 cases being reported throughout the country, challenges may still exist that hinder access to testing for some patients.

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. 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 recommendations by an additional 3 months (until September 30, 2021).

These recommendations for blood testing 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 status. You will be updated regarding any future changes to the requirements.

Side Effect Precaution

Health Canada is aware of documented cases in the literature of increased clozapine levels associated with toxic effects in the setting of inflammation and infection. Health Canada is asking HLS Therapeutics Inc. to inform prescribers of this potential risk in various clinical situations, including in the setting of the ongoing pandemic, and to closely monitor patients based on the individual clinical situation. Health Care Providers should be encouraged to report any related cases.

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	(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 Region	Sophie Ferland	(418) 563-7938
West Coast	Moriah Tate	(780) 281-1332

Please note, **CSAN® Pronto™**, a **point of care capillary testing program**, to simplify access to routine WBC and ANC monitoring for CLOZARIL® patients is now available. For more information, please contact CSAN®.

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.² For more information the product monograph may be accessed at www.Clozaril.ca.