

January 28, 2021

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

Dear Health Care Professionals;

Throughout 2020, Health Canada had issued interim recommendations that could be implemented by Health Care Professionals that were managing patients treated with ^{Pr}CLOZARIL[®] during the COVID-19 pandemic.

Health Canada has confirmed it's previous guidance remains in effect as noted:

Health Canada has reviewed the submitted information for clozapine, and no emerging safety concerns have been identified for the period of mid-March to the end of November 2020. As Canada remains in the second wave of the COVID-19 pandemic at the current time, Health Canada recognizes that access to testing for some patients remains an ongoing challenge. However, 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 (HCPs) should continue to use their best clinical judgment in weighing the benefits and risks of continuing treatment in the absence of laboratory testing. HCPs should also communicate with their patients regarding these safety considerations, including the associated risks.

Considering that Canada remains in the second wave of the COVID-19 pandemic, Health Canada's assessment of the current situation supports extending the current recommendations by an additional sixmonths. If there is a missing or delayed laboratory test, the reason should be properly documented and reported to Health Canada by $CSAN^{\&.1}$

The CSAN[®] Program is now using the 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 CSAN.

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 (800) 267-2726.

Region	Nurse Educator	Phone Number
Ontario West	Christopher Komel	(647) 244-0765
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

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References: ¹ Health Canada Correspondence to HLS Therapeutics Inc Jan 22, 2021 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



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

Sincerely,

Allo

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.

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