



Health
Canada

Santé
Canada

Health Products
and Food Branch

Direction générale des produits
de santé et des aliments

Marketed Health Products Directorate
A.L. 1906 C
OTTAWA, Ontario
K1A 0K9

December 01, 2020

20-114989-482

To whom it may concern,

Re: Health Canada will publish a summary safety review regarding direct-acting antiviral products containing a protease inhibitor

As an ongoing commitment to openness and transparency, Health Canada would like to notify you that a summary safety review (SSR) regarding direct-acting antiviral products containing a protease inhibitor and the potential risks of hepatic decompensation and hepatic failure will be published (see attached document). The SSR is intended to provide Canadians with a sufficient understanding of the safety review conducted by Health Canada, specifically what was assessed, what was found and what action was taken. The SSR will be posted in subsequent days.¹

This advance notification is being sent for your information only. A broader dissemination to your members would be greatly appreciated.

Any question related to the SSR process or requests for further information on the safety review should be directed to the Marketed Health Products Directorate; e-mail: hc.mhpdssrcoordinator-dpscreicoordinateur.sc@canada.ca

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¹ <http://www.hc-sc.gc.ca/dhp-mps/medeff/reviews-examens/index-eng.php>

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Please feel free to contact us, should you require further information.

Sincerely,

E-signed by

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Office of Policy, Risk Advisory and Advertising
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Attachment:

Summary Safety Review – Direct-acting antiviral products containing a Protease Inhibitor
- Assessing the Potential Risks of Hepatic Decompensation and Hepatic Failure