



Important Supplementary Information for NARCAN[®] Nasal Spray 4 mg

NARCAN[®] Nasal Spray 4 mg (naloxone hydrochloride) has been approved for sale in the United States (U.S.) by the U.S. Food and Drug Administration. It has not yet been authorised for sale in Canada. However, in order to provide earlier access to Canadians and to reduce harms associated with opioid overdose, the Minister of Health has signed an Interim Order under the *Food and Drugs Act* allowing the importation and sale of NARCAN[®] Nasal Spray 4 mg, as approved in the U.S., for a period of up to one year.

Risk Statements

- Health Canada would like to advise that the use of NARCAN[®] Nasal Spray in young children and pregnant women may not be appropriate. Availability of other naloxone products, such as naloxone hydrochloride injection, may be more appropriate. Ask your pharmacist about other treatment options.
- NARCAN[®] Nasal Spray has been approved by the U.S. Food and Drug Administration for prescription use. The attached [U.S. Prescribing Information](#) was therefore developed to reflect prescription use. Some of the information found in the U.S. Prescribing Information may not be relevant for its use in Canada. For example, do not report any side effects to the U.S. Food and Drug Administration, but rather as per the information provided below.

Reporting Side Effects

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You can report any suspected side effect associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. Health Canada does not provide medical advice.