

June 23, 2020

Audience: Healthcare professionals prescribing, dispensing and/or administering salbutamol inhalation aerosol

Salbutamol Sulfate Metered Dose Aerosol, 100mcg per Actuation Importation of Philippine-authorized Salbuhaler Stock due to Shortage

Key messages

- There is an increased demand and shortage of salbutamol metered-dose inhalers (MDIs) in Canada due to the COVID-19 pandemic.
- Given the medical necessity of salbutamol, Health Canada has added Sandoz-Philippines authorized Salbuhaler MDI (100 mcg salbutamol/metered dose) to the List of Drugs for Exceptional Importation and Sale. Sandoz Canada Inc. is importing Philippine-authorized Salbuhaler product manufactured in Germany with an English label for sale in Canada.
- Salbuhaler (salbutamol sulfate), shares the same indications, strength and dosage form as salbutamol inhalers on the Canadian market.
- Salbuhaler contains the active ingredient, salbutamol sulfate, and the following non-medicinal ingredients: norflurane (HFA 134a), anhydrous ethanol and oleic acid.
- Healthcare professionals are advised that:
 - Salbuhaler (salbutamol sulfate) shares the same indications, strength and dosage form as salbutamol inhalers on the Canadian market.
 - Salbuhaler (salbutamol sulfate) product should be stored at temperatures not exceeding 25°C.
 - Salbuhaler (salbutamol sulfate) is required to be primed by spraying twice in the air for first time use or if not used for more than 7 days, which differs from similar Canadian inhalers.
 - Salbuhaler (salbutamol sulfate) may be used with a spacer device by patients or children who find the coordination of a pressurized metered dose difficult.
 - Salbuhaler (salbutamol sulfate) consumer information does not include specific cleaning instructions. The inhaler should be cleaned regularly by removing the canister, rinsing the mouthpiece with running water, and drying thoroughly. If the inhaler becomes blocked the mouthpiece should be washed.

- Salbuhaler (salbutamol sulfate) should be dispensed and prescribed using the same dosing recommendations as for Canadian salbutamol inhalers.
- Healthcare professionals are reminded to carefully review the product monographs for salbutamol inhalers on the Canadian market for a full list of contraindications, warnings and precautions and serious life-threatening drug interactions.

<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>

Report on health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving temporarily imported Salbuhaler (salbutamol sulfate) should be reported to Sandoz local Patient Safety Department or Health Canada.

Sandoz Canada Patient Safety Department:

Email: drug.safety@novartis.com

Fax number: 1-877-636-3175;

Online: <https://www.report.novartis.com>

To correct your mailing address or fax number, contact Sandoz Canada.

Adverse Reactions associated with the use of Salbuhaler (salbutamol sulfate) can be reported to Health Canada at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

Original signed by

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