

Importation of UK-Labelled Teva-Salamol CFC-Free (Salbutamol Sulfate) Inhaler due to Shortage

Due to an increase in demand and a shortage of salbutamol inhalers in Canada caused by the COVID-19 pandemic, Health Canada has allowed the importation of a limited supply of Teva's United Kingdom (UK)-labelled salbutamol inhaler, Salamol CFC-Free (Salbutamol Sulfate Pressurized Inhalation Suspension) 100 mcg salbutamol per metered dose, which is manufactured by IVAX Pharmaceuticals Ireland (Teva Pharmaceutical Industries) with the UK-labelled product identifier of PL 00530/0555.

Please note: A temporary Product Identification Number has been assigned to Salamol CFC-Free 100 mcg / Dose Metered Dose Aerosol (PIN 09858115).

The UK-labelled salbutamol inhalers have the same active ingredient and are identical in concentration as salbutamol inhalers on the Canadian market, and are used in a comparable way. Health professionals are advised that the preparation for use instructions for the UK-labelled salbutamol inhaler may differ from those for the Canadian inhalers. Before using the UK-labelled salbutamol inhaler for the first time, or if it has not been used for 5 days or more, **2 sprays should be released** into the air to ensure it is working properly.

Healthcare professionals are also advised to follow the Canadian dosing recommendations when using, prescribing, or dispensing UK-labelled salbutamol inhaler for children 4–11 years of age of a **maximum 4 sprays (400 mcg salbutamol) per day**.

Pharmacists and other healthcare professionals are reminded to:

- Inform patients that they are receiving a UK-labelled product.
- Print the Health Canada communication and make it available to patients and caregivers upon dispensing the UK-labelled product. The communication is available at: <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73095a-eng.php>
- Review the preparation for use instructions for the UK-labelled inhaler with the patient when dispensing this product.
- Remind caregivers that the maximum recommended daily dose is 4 sprays for children 4-11 years of age.
- Consult the Canadian product monograph for prescribing information as well as important safety information on salbutamol inhalers found on Health Canada's Drug Product Database at: <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>
- Supply only one inhaler at a time when patients go to refill their prescriptions, to manage and conserve supply.

Temporary Benefit added to the *Alberta Drug Benefit List (ADBL)*

Due to the unavailability of the following products, Salamol CFC-Free 100 mcg / Dose Metered Dose Aerosol (Temporary PIN 09858115) will be considered as a temporary benefit for the *Alberta Drug Benefit List (ADBL)*.

DIN	Product Description
02232570	Airomir CFC-Free 100 mcg/Dose Metered Dose Aerosol
02419858	Apo-Salbutamol HFA 100 mcg/Dose Metered Dose Aerosol
02245669	Salbutamol HFA 100 mcg/Dose Metered Dose Aerosol
02241497	Ventolin HFA 100 mcg/Dose Metered Dose Aerosol

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As of **May 16, 2020** all claims for the below product will be adjudicated to the price of **\$0.0273 per dose**.

PIN	Product Description	Unit Price
09858115	Salamol CFC-Free 100 mcg / Dose Metered Dose Aerosol	\$0.0273

Alberta Blue Cross will continue to monitor the availability of the shorted products and potential alternatives, in addition to working with other provinces and territories, manufacturers, and Health Canada to address this shortage and minimize the impact on Albertans.

This product is subject to the usual review process by the Expert Committee on Drug Evaluation and Therapeutics and must be approved by the Minister of Health to remain as a benefit.

Temporary change to Step Therapy for Direct-Acting Oral Anticoagulants (DOACs) on the *Alberta Drug Benefit List (ADBL)* effective May 15, 2020 for government-sponsored programs

In light of the COVID-19 pandemic, Alberta Health is making a temporary change to Step Therapy for Direct-Acting Oral Anticoagulants (DOAC) for the treatment of patients who are at-risk with non-valvular atrial fibrillation, or have experienced a deep vein thrombosis (DVT) / pulmonary embolus (PE). Effective immediately, these products are eligible for all patients with these indications where anticoagulation with warfarin is not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing while social distancing measures are in place. This change affects the following products:

- Apixaban (e.g. Eliquis)
- Dabigatran (e.g. Pradaxa)
- Edoxaban (e.g. Lixiana)
- Rivaroxaban (e.g. Xarelto)

Claims processes

If a claim for these products is rejected for one of the above listed indications, pharmacists can use their professional judgement to determine if monitoring via INR testing is possible in light of social distancing measures. If INR testing is not possible, the pharmacist is responsible to document this on the patients record and re-submit the claim with the following intervention code:

- NB = valid claim - validation on file

Please note: This temporary change is being granted for the duration of the COVID-19 pandemic only and will not be reflected on the *ADBL*. All other criteria as defined for these products on the *ADBL* still apply. At such time that regular INR testing capacity returns to normal levels, this code will be deactivated, and requests for coverage of DOAC drugs will revert to the previous Special Authorization requirements.

When you have questions:

For assistance with benefit or claim inquiries, please contact an Alberta Blue Cross Pharmacy Services Provider Relations contact centre representative at:

780-498-8370 (Edmonton and area) • **403-294-4041** (Calgary and area) • **1-800-361-9632** (toll free)

FAX 780-498-8406 (Edmonton and area) • **FAX 1-877-305-9911** (toll free)

Alberta Blue Cross offers online access to current Pharmacy Benefits and supplemental claiming information to assist with the submission of your direct bill drug claims. Visit ab.bluecross.ca/providers/pharmacy-home.php

