

Frequently Asked Questions – Executive Officer Notice: Funding of Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler as a Temporary Benefit on the Ontario Drug Benefit (ODB) Formulary

Last Updated May 26, 2020

1. **If I have a prescription that specifies a particular brand of salbutamol in Canada but all I have in stock is Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler, can I adapt the prescription to dispense the Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler?**

No. A pharmacist may only adapt a prescription (new or refill) by altering the dose, dosage form, regimen or route of administration, based on their professional judgement and the circumstances of the individual patient, in order to ensure continuity of care for the patient. As dispensing Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler in place of a listed interchangeable version of salbutamol would be a question of interchangeability, this would not fall within the scope of adapting a prescription. Since Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler **is not interchangeable** with other salbutamol inhaler products funded on the ODB Formulary as a General Benefit, a new prescription would need to be requested specifically authorizing the dispensing of Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler. Alternatively, the prescriber may authorize the dispensing of a particular strength and dosage of salbutamol **without** specifying a specific brand or product name, which would also permit a pharmacist to dispense Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler, of the same strength and dosage noted in the prescription, if no listed interchangeable version is available in pharmacy stock.

2. **What documentation is required to dispense Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler? Do I need to prove that I have no other listed interchangeable version of salbutamol inhaler in stock prior to dispensing it?**

If, Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler is dispensed because regular General Benefit salbutamol inhaler products are not available, pharmacists should document this on the prescription hard copy; no other proof of inventory is required. Additionally, any required documentation associated with standard dispensing practices

continues to be required. Pharmacy documentation must be maintained in a readily available format for the purpose of post-payment verification and inspection for a minimum of two years.

3. What information do I need to provide the patient when dispensing Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler?

Prior to dispensing Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler, pharmacists should consult Health Canada's [Important Safety Information – Importation of Teva UK-labelled ^{Pr}Salamol CFC-Free \(Salbutamol Sulfate\) Inhaler due to Shortage](#).

When dispensing this product, pharmacists should:

- Inform patients that they are receiving a UK-labelled product, which delivers the same labelled dose of the same active ingredient as the Canadian product.
- Print the Health Canada communication and make it available to patients and caregivers upon dispensing the UK-labelled product.
- Review the preparation for use instructions for the UK-labelled inhaler with the patient when dispensing this product and advise to follow the UK-labelled instructions for inhaler preparation.
- Remind caregivers to follow the Canadian labelled maximum recommended daily dose for children 4-11 years of age: maximum 4 sprays (400 mcg salbutamol) per day.
- Supply only one inhaler at a time when patients refill their prescription, to manage and conserve supply.
- Consult the Canadian product monograph for other prescribing information as well as important safety information on salbutamol inhalers at Health Canada's [Drug Product Database](#).

4. The Notice says that Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler is funded on the ODB Formulary effective May 29, 2020 as a temporary benefit. When this is removed, can I continue to dispense Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler until my inventory is depleted?

Pharmacies should manage and maintain inventory levels to support continuity of patient care as best as possible, while avoiding stockpiling. Pharmacies are encouraged to check with their wholesalers regarding return policies for Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhalers. OPA has requested additional clarification from the Ministry to ensure that pharmacies are provided sufficient advance notice prior to the removal of this temporary benefit and will update these FAQs to share with members when more information is available.

- 5. The wholesaler indicates that a listed interchangeable version of salbutamol inhaler is in stock, but it was not shipped in my order. Can I continue to dispense Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler?**

Yes. Pharmacies should follow-up with their wholesaler to determine why the product was not shipped; however, Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler can be dispensed if a regular General Benefit salbutamol inhaler product is not available in stock at the pharmacy. Once pharmacies have listed interchangeable versions of salbutamol inhalers in stock, those should be dispensed instead of the Teva UK-labelled product.

- 6. I have a prescription that specifically authorizes the dispensing of Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler, but I have other listed interchangeable versions of salbutamol inhaler in stock. Can I dispense Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler?**

Pharmacies should dispense salbutamol products reimbursed on the ODB Formulary as regular General Benefits if they are available. Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler should only be dispensed in situations where salbutamol is required but not in stock at the pharmacy. Therefore, if other listed interchangeable versions of salbutamol inhalers are in stock, the dispenser should try to contact the prescriber to have that prescription changed to dispense a salbutamol product that is reimbursed on the ODB Formulary as a regular General Benefit. However, pharmacists are reminded to practice in accordance with the Ontario College of Pharmacists' Standards of Practice and Code of Ethics and exercise professional judgement in exceptional cases to ensure continuity of care for patients.

- 7. When the other listed interchangeable versions of salbutamol inhaler come back in stock, should I switch patients who have received Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler back to a listed interchangeable version?**

Yes. Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler should only be dispensed if a regular General Benefit salbutamol inhaler product is not available. Pharmacies should revert to dispensing salbutamol inhaler drug products listed as regular General Benefits on the ODB Formulary once they have supply in stock. Please refer to Question 6 above for the situation when the original prescription specifically authorizes the dispensing of the Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler. If the original prescription authorizes the dispensing of a particular strength and dosage of salbutamol **without** specifying a specific brand or product name, the prescriber does not need to be contacted to switch patients back to a listed interchangeable version.

8. Is Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler covered by other private third-party insurance plans?

The interim approval of the Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler means that it does not carry an official drug identification number (DIN). Coverage for ODB patients is accomplished via creation of a pseudo-DIN (PIN). This PIN is only applicable to ODB-eligible claims. Patients with a private third-party insurance plan should contact the plan adjudicator to confirm coverage of Teva UK-labelled ^{Pr}Salamol CFC-Free (Salbutamol Sulfate) Inhaler. OPA is conferring with the Canadian Life and Health Insurance Association (CLHIA) on this matter and will share information once it becomes available.