

GLAXOSMITHKLINE PRODUCT ADVISORY

Date: 19 September 2025

Dear Healthcare Professional,

Title: Salbutamol pressurized metered dose inhaler – reinforcing information regarding number of prescribed doses available

This letter is to reinforce information about salbutamol pressurized metered dose inhaler (pMDI) in relation to the number of prescribed doses available as per the label.

The inhaler contains enough salbutamol for 200 actuations (puffs) only. After 200 actuations (puffs), the inhaler can continue to spray but without the prescribed dose of salbutamol.

Key Messages

- Methods such as shaking, weighing or submerging inhalers are not accurate for determining that an inhaler is empty of the prescribed dose of salbutamol.
- Accordingly, maintaining a record of the number of actuations (puffs) administered to the patient should be considered towards avoiding inadvertent use of an empty inhaler.
- Patients keeping a back-up inhaler could be considered. If the patient has more than one inhaler, it is recommended to keep track of each inhaler separately.

Action required by Healthcare Professionals

Healthcare Professionals should reinforce this information with their patients.

Revised Labeling

At this time, we would like to inform you about a regulatory submission for a variation related to VENTOLIN EVOHALER 100mcg, which will be made to the Ministry of Public Health Republic of Lebanon (if needed). This variation will include updates to the product labeling designed to enhance patient safety and provide clearer guidance on the use of VENTOLIN EVOHALER 100mcg.

Specifically, the proposed changes to the labeling aim to address the following:

Addition of Precautionary Measures: To mitigate the potential risk of inadvertent use of an empty salbutamol pressurized metered dose inhaler (PMDI).

Update to the Existing Warning Statement: To further emphasize the importance of patients seeking medical advice when appropriate.

The sections impacted by these proposed changes include:

Formulation and Strength

Nature and Contents of Container

Use and Handling

Warnings and Precautions

These updates are intended to ensure that healthcare professionals and patients are better equipped to identify and address potential risks associated with the use of VENTOLIN EVOHALER 100mcg.

Further Information

In addition, regarding the occurrence of adverse reactions after the administration of the drug, please report to GlaxoSmithKline Export Limited: by e-mail: pm.safety@gsk.com or by using Reportum platform: <https://gsk.public.reportum.com/>

or to the Ministry of Public Health: by e-mail: pv@moph.gov.lb or to the National Center of Pharmacovigilance at the Lebanese University: by e-mail phvg.phar@ul.edu.lb.

Contact(s) for Further Information or Questions

For all questions, please contact: pm.safety@gsk.com