

**Salbutamol pressurized metered dose inhaler (pMDIs), Ventolin 100 mcg Evohaler: reinforcing information regarding number of prescribed doses available**

18<sup>th</sup> June 2025

*Dear Healthcare Professional,*

This letter is provided by GSK and is being sent in agreement with the Saudi Food and Drug Authority is to reinforce information about salbutamol pressurized metered dose inhaler (pMDIs), Ventolin 100 mcg Evohaler, without dose counters in relation to the number of prescribed doses available as per the label.

**Summary:**

- 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.
- 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.

**Further information and recommendations:**

To reinforce the number of prescribed doses available in the salbutamol pMDI and optimize the use without a Dose Counter, GSK recommends Healthcare Professionals should convey this information to their patients to further support appropriate patient use and mitigate the potential risk of inadvertent use of an empty salbutamol pMDI. Please forward this information to relevant staff members in your organisation dealing with the product

## Direct Healthcare Professional Communication



### **Call for reporting:**

By reporting side effects, you can help provide more information on the safety of this medicine.

To report Adverse Event/s associated with the use of GSK product/s, please contact GSK via:

Phone: +966 56 904 9882

Email: [saudi.safety@gsk.com](mailto:saudi.safety@gsk.com).

For any side effect(s), please contact The National Pharmacovigilance Centre (NPC- Saudi Food and Drug Authority (SFDA):

SFDA call center: 19999

E-mail: [npc.drug@sfd.a.gov.sa](mailto:npc.drug@sfd.a.gov.sa)

Website: <http://ade.sfd.a.gov.sa/>



For further information, please refer to the Patient Information Leaflet (PIL)

on Saudi Drug Information website: <https://sdi.sfd.a.gov.sa>

or contact GSK via:

Phone: +966 12 653 6666

Email: [gcc.Medinfo@gsk.com](mailto:gcc.Medinfo@gsk.com)



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Yours sincerely

Hany Soliman

GSK Country Medical Manager, Saudi Arabia

## **References**

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2. Kaur I, Aggarwal B, Gogtay J. Integration of dose counters in pressurized metered-dose inhalers for patients with asthma and chronic obstructive pulmonary disease: Review of evidence. *Expert Opin Drug Deliv.* 2015;12(8):1301-10.
3. National Child Mortality Database (NCMD). National Child Mortality Database Programme Thematic Report. Child deaths due to Asthma or Anaphylaxis. Data from April 2019 to March 2023. December 2024.