

01/01/2023

#### **Direct Healthcare Professional Communication**

Salbutamol 5 mg/ml (As Sulphate) - BRONCHOVENT 5 mg/ml Nebulizer Solution for Inhalation in multiple use glass vials, this letter focusing on increase awareness for healthcare providers to the potential error and reduce the chance of misunderstanding in practice.

#### Dear Healthcare professional,

Pharmaceutical Solutions Industry in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform that the correct use of Bronchovent to avoid potential wrong route administration error.

## Summary

- Bronchovent is a short-acting, selective beta2-adrenergic receptor agonist approved by the Saudi food and drug Authority which is indicated for use in routine management of chronic bronchospasm unresponsive to conventional therapy, and for treatment of acute severe asthma.
- It is for inhalation use only, to be breathed in through a mask, under the direction of a physician, using a suitable nebuliser.
- It has duration of action of 4 to 6 hours in most patients.
- Bronchovent Nebulizer Solution must <u>only be used by inhalation</u>, and <u>must not be injected or swallowed</u>.
- Bronchovent Nebulizer Solution may be administered intermittently or continuously.
- Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma.
- Bronchovent Nebulizer Solution should be used with care in patients known to have received large doses of other sympathomimetic drugs.
- The content should be used within one month after the vial is opened.

The product information for Bronchovent medicine will be updated accordingly.



The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

#### List of product:

Active substance	Brand name
Salbutamol 5 mg/ml (As Sulphate)	BRONCHOVENT 5 mg/ml

# Call for reporting

Call for reporting for adverse reactions:

## The National Pharmacovigilance (NPC)

SFDA Call Centre: 19999

Email: NPC.drug@sfda.gov.sa

Website: https://ade.sfda.gov.sa/

## **Company Contact Point:**

Pharmaceutical Solutions Industry Ltd.

Phone: +966-12-6361383 ext: 239

FAX: +966-12-6379460

Website: http://www.psiltd.com

Email: phvigilance@psi.com.sa

01/01/2023

Name of QPPV:

Waad S. Alfahmi