





Ventolin Nebules (salbutamol sulfate) 2.5mg/2.5mL inhalation solution ampoules supply outage

Guidance for health professionals in primary care

An anticipated supply outage of salbutamol sulfate 2.5mg/2.5mL inhalation solution ampoules (Ventolin nebules) has been reported by the manufacturer GlaxoSmithKline (GSK).

PBS clinical criteria

For both asthma and Chronic Obstructive Pulmonary Disease (COPD), a patient must be **unable to use this drug (salbutamol) delivered from an oral pressurised inhalation device via a spacer**.

Check the Pharmaceutical Benefits Scheme (PBS)¹ and Therapeutics Goods Administration (TGA)² for up-to-date population, age, and clinical criteria for this product.

Full product information can be found here.



Pressurised metered dose inhalers (pMDI) plus spacer continue to be the recommended bronchodilator delivery system for patients with asthma or COPD. The use of pMDI and spacer is just as effective as using nebulisers in people with asthma³ and COPD⁴.

Why is there an outage?

According to the manufacturer, GSK, the outage is due to an unexpected increase in demand within the community setting and limited scope to adjust the manufacturing capacity to meet the demand. There are no concerns with the quality of the product currently supplied in Australia. The anticipated temporary supply outage does not apply to salbutamol 5.0mg/2.5mL inhalation solution or any other inhaler device containing salbutamol.

When will the outage end?

Based on current information, provided by the TGA, the supply outage is anticipated from 15 November 2023, to 1 August 2024. For up-to-date information on the anticipated supply outage visit the TGA website: **Medicines Shortage Reports Database**.

Alternative options for day-to-day treatment

To ensure the availability of supply for emergency situations and for patients who have no alternative, consider the following options for patients with chronic airways disease who are currently prescribed nebulised Ventolin:

1. Prescribe alternative treatments for patients where clinically appropriate

Using a pMDI and spacer is just as effective as a nebuliser in people with asthma⁵ and COPD⁶. The degree of bronchodilation achieved reflects the dose of bronchodilator administered and not the mode of administration^{3,4,7}.

Patients who use nebulised salbutamol should be switched to salbutamol pMDI and spacer (plus mask where appropriate, e.g. children under 4 years old, older patients).

When initiating patients on salbutamol, this should be via pMDI and spacer and not nebulised salbutamol unless clinically necessary.

This should also include inhaler and spacer technique demonstration and the provision of an **asthma** or **COPD Action Plan**, specifying the required numbers of puffs of salbutamol via a spacer and the relevant techniques for the context of day-to-day use versus emergency use.

2. Transition from nebules to pMDI following acute exacerbations

For hospital patients who require nebulised salbutamol for a severe acute episode, change to pMDI and spacer as soon as clinically appropriate.

3. Reduce script quantities and repeats

For patients for whom a pMDI and spacer is not an option, only prescribe the quantity and number of repeats that are clinically necessary for the patient, rather than the PBS maximum quantities (3 boxes of 20 nebules with 5 repeats) by default.

4. Review maintenance treatment

Review asthma or COPD maintenance medication to ensure this is optimised for symptom prevention and control, and for reduction in exacerbations, as this will reduce the need for short acting bronchodilator, including by nebuliser. Alternative treatment to salbutamol inhalation solution ampoules may not be clinically appropriate for some patients with chronic airways disease, such as some patients with:

- co-existing lung conditions (e.g. bronchiectasis, cystic fibrosis)
- disability and/or comorbidities (e.g. cognitive impairment, manual dexterity issues), if the patient is not able to be trained to use a pMDI and spacer.

Accessing salbutamol 2.5mg/2.5mL inhalation solution

With the outage of salbutamol 2.5mg/2.5mL inhalation solution present until 1 August 2024, it is likely to become unavailable following the dispensing of residual stock.

It is expected that many wholesalers will be out of stock by mid-end November. For any further information on stock availability for salbutamol 2.5mg/2.5mL inhalation solution please contact GSK medical information on 1800 033 109.

Patients should be referred to their treating health professional to prioritise review of their treatment and management to avoid the time and administrative burden on patients and health professionals sourcing supply.

Visit the TGA for more information on accessing medicines during an outage.

FURTHER INFORMATION

Refer to the relevant Product Information, the **COPD-X Guidelines** and **Australian Asthma Handbook**, and other appropriate guidelines when determining management options for your patients.

For ongoing supply updates for salbutamol 2.5mg/2.5mL inhalation solution, visit the TGA website.

- Medicines shortages: Information for health professionals
- · Medicines shortages: Information for consumers

Lung Foundation Australia 1800 654 301 lungfoundation.com.au Asthma Australia 1800 ASTHMA (1800 278 462) **asthma.org.au**

- 1. https://www.pbs.gov.au/medicine/item/11125M-11130T
- 2. https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-05107-3
- 3. Cates CJ, Welsh EJ, Rowe BH. Holding chambers (spacers) versus nebulisers for beta agonist treatment of acute asthma. Cochrane Database of Systematic Reviews 2013, Issue 9. Art. No.: CD000052. DOI: 10.1002/14651858.CD000052.pub3. Accessed 25 July 2023.
- 4. van Geffen WH, Douma WR, Slebos DJ, Kerstjens HAM. Bronchodilators delivered by nebuliser versus pMDI with spacer or DPI for exacerbations of COPD. Cochrane Database of Systematic Reviews 2016, Issue 8. Art. No.: CD011826. DOI: 10.1002/14651858.CD011826.pub2. Accessed 25 July 2023.
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- 6. van Geffen WH, Douma WR, Slebos DJ, Kerstjens HAM. Bronchodilators delivered by nebuliser versus pMDI with spacer or DPI for exacerbations of COPD. Cochrane Database of Systematic Reviews 2016, Issue 8. Art. No.: CD011826. DOI: 10.1002/14651858.CD011826.pub2. Accessed 25 July 2023.
- 7. Mestitz H, Copland JM, McDonald CF. Comparison of outpatient nebulized vs metered dose inhaler terbutaline in chronic airflow obstruction. Chest. 1989 Dec;96(6):1237-40. doi: 10.1378/chest.96.6.1237. PMID: 2582827.

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