Chief Medical Officer Directorate Pharmacy and Medicines Division



17 July 2024

## Medicine Supply Alert Notice

# Ipratropium bromide 250micrograms/1ml and 500micrograms/2ml nebuliser liquid unit dose vials

# Priority: Level 2 Valid until: late March 2025

#### Issue

- 1. Ipratropium bromide 250micrograms/1ml and 500micrograms/2ml nebuliser solution is in limited supply until late March 2025.
- 2. Ipratropium bromide 20microgram/dose inhalers remain available and can support an increase in demand.
- 3. Salbutamol 2.5mg/2.5ml / ipratropium bromide 500micrograms/2.5ml nebuliser solution remains available, however, cannot support an increase in demand.
- 4. Unlicensed supplies of ipratropium bromide 250micrograms/1ml and 500micrograms/2ml nebuliser solution have been sourced, lead times vary.
- 5. Access to licensed ipratropium nebules will be actively monitored. Where possible, supplies will be prioritised for ambulance services who are less able to use unlicensed supplies.

## Advice and Actions

- 6. Existing supplies of ipratropium nebules should be prioritised for the management of severe airflow obstruction, such as in acute asthma and exacerbations of chronic obstructive pulmonary disease (COPD), and in patients with a tracheostomy for whom the nebulised route may be more suitable.
- 7. For all other patients in primary and secondary care, clinicians should:
  - review the need for ipratropium nebules;
  - consider prescribing ipratropium 20microgram/dose inhaler via a spacer device, where appropriate, ensuing inhaler counselling is provided;
  - ensure patients recovered from an exacerbation of COPD are switched from the nebules back to their usual long-acting muscarinic antagonist (LAMA) inhaler as soon as possible; and
  - consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see additional information).

#### **Additional Information**

\*https://www.nss.nhs.scot/media/1842/medicine-supply-alert-notices-definitions-of-classifications-21-october-2019.pdf

#### **Clinical information**

- 8. Ipratropium is a short-acting muscarinic antagonist. The nebules, when used concomitantly with inhaled beta2-agonists, are licensed for the treatment of reversible airways obstruction as in acute and chronic asthma. They are also licensed for the treatment of reversible bronchospasm associated with COPD. The inhaler is licensed for the regular treatment of reversible bronchospasm associated with COPD and chronic asthma.
- 9. For an acute severe asthma attack, BTS guidance notes combining nebulised ipratropium bromide with a nebulised beta2 agonist produces significantly greater bronchodilation than beta2 agonist alone, leading to faster recovery and shorter duration of admission. It points out that anticholinergic (antimuscarinic) treatment is not necessary and may not be beneficial in milder asthma attacks or after stabilisation.
- 10. NICE guidance suggests both nebulisers and hand-held inhalers can be used to administer inhaled therapy during exacerbations of COPD. The choice of delivery system should reflect the dose of drug needed, the person's ability to use the device, and the resources available to supervise therapy administration. It is recommended that patients are changed to hand-held inhalers as soon as their condition has stabilised, because this may allow them to be discharged from hospital earlier.

#### Links to further information

- <u>SmPC: ipratropium nebuliser solution</u>
- BNF: ipratropium
- <u>NICE guideline (NG115): COPD in over 16s: diagnosis and management-exacerbations BTS</u> guidelines on the Management of Asthma

## Guidance on ordering and prescribing unlicensed imports

- 11. The following specialist importers have confirmed they can source unlicensed supplies of ipratropium 250micrograms/1ml and 500micrograms/2ml nebuliser solution (please note there may be other companies that can also source supplies):
  - Alium Medical
  - Clinigen
  - QMed
  - Smartway
  - Target Healthcare
- 12. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and Health Board or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes. Please see the links below for further information:
  - <u>The supply of unlicensed medicinal products</u>, Medicines and Healthcare products Regulatory Agency (MHRA)
  - <u>Professional Guidance for the Procurement and Supply of Specials</u>, Royal Pharmaceutical Society
  - <u>Prescribing unlicensed medicines</u>, General Medical Council (GMC).

#### Specialist Pharmacy Service (SPS) website

- 13. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the <u>SPS website</u>. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 14. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

#### Enquiries

 Enquiries from Health Boards or healthcare professionals should be directed in the first instance to <u>PharmacyTeam@gov.scot</u> (primary care) or <u>NSS.NHSSMedicineShortages@nhs.scot</u> (secondary care).