National Patient Safety Alert

Department of Health & Social Care

NHS England

# Discontinuation of Promixin® (colistimethate) 1-million unit powder for nebuliser solution unit dose vials

| Date of issue: | 17-Mar-25 | Reference no: | NatPSA/2025/001/DHSC |
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This alert is for action by: All organisations involved in prescribing and dispensing Promixin® (colistimethate) 1million unit powder for nebuliser solution unit dose vials.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in pharmacy, community pharmacy, GP practices and clinical leaders in respiratory and cystic fibrosis.

## Explanation of identified safety issue:

Promixin® (colistimethate) 1-million-unit powder for nebuliser solution unit dose vials (UDVs) are being discontinued from early May 2025, with stocks anticipated to be exhausted by this date.

As a result of the discontinuation of I-neb devices, discs and consumables from an external manufacturer, which are compatible with Promixin® (colistimethate) 1million unit powder for nebuliser solution unit dose vials, it is no longer viable to manufacture further supplies of the drug.

Promixin® (colistimethate) 1million unit powder for nebuliser solution unit dose vials are licensed for the treatment of adult and paediatric chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis. This treatment may also be prescribed for the treatment of Pseudomonas aeruginosa colonisation and infection in adult and paediatric patients with non-cystic fibrosis bronchiectasis or bronchial sepsis.

Colicym® (colistimethate) 1million-unit powder for nebuliser solution unit dose vials are available and can support an increase in demand.

Colomycin® (colistimethate) 1million-unit and 2million-unit powder for solution for injection, infusion or inhalation vials are in limited supply until mid- April 2025 and late March respectively and are currently unable to support any increase in demand until the resupply dates.

The SPS Medicines Supply Tool provides an overview of the supply situation and will be updated if there are subsequent changes to this communication, including resupply dates.

## Actions required

**Actions to be completed by** 30/04/2025

Primary and secondary care providers:

1. Do not initiate new patients on Promixin® 1-million-unit powder for nebuliser solution UDVs.
2. Pro-actively identify and review all patients currently prescribed Promixin® 1million unit powder for nebuliser solution UDVs and immediately refer them to their respiratory specialist to switch to an alternative colistimethate preparation.

Respiratory specialists within secondary care should consider the patients diagnosis and:

1. Consider prescribing Colicym® 1-million-unit powder for nebuliser solution unit dose vials.[NOTE A]
2. Where the above is not suitable, prescribe Colomycin® 1-million- or 2-million-unit powder for solution for injection, infusion or inhalation. [NOTE B]
3. When switching colistimethate products, ensure patients are provided with appropriate education and training to ensure they can use the new nebuliser device and administer the correct dose.
4. Once switched to an alternative colistimethate product, clinicians in secondary care should ensure this is documented and shared with primary care, for on-going treatment, where applicable.
5. Homecare providers should ensure affected patients are notified of any changes to their prescribed medicines and are aware of any changes to their homecare provisions.



Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

## Additional information:

### Clinical Information

When switching patients from Promixin® to an alternative colistimethate preparation, individual summary of product characteristics (SmPCs) should be consulted as the products vary in indications, dosing and administration. Switching from Promixin® to alternative colistimethate preparations should be carried out under specialist supervision to ensure patients understand how to use the new nebuliser device and administer the correct dose. The respiratory team should risk assess the need for a test dose and ensure if needed this is administered under clinical supervision.

All equipment (diluents, nebuliser device and needles) will be supplied via Respiratory teams.

**Note A: CAUTION:**
**Colomycin® is licensed for administration via both the intravenous and inhaled route.**
**Colicym® is only licensed for nebulisation.**
**Care should be taken to ensure the correct product has been selected when dispensing and administering colistimethate products.**

**Note B:** Colomycin® (colistimethate) 1-million and 2-million unit powder for solution for injection, infusion or inhalation vials are in limited supply until mid-April and late March 2025 respectively and unable to support an increase in demand until these dates.

Current stock should be reserved for patients already maintained on this treatment or for those who require treatment via the intravenous route.

**References:**


1. SmPC Promixin® 1 million international units (IU) powder for nebuliser solution
2. SmPC Colomycin® 1million international units (iu) powder for solution for injection, infusion or inhalation
3. SmPC Colicym® powder for nebuliser solution
4. BNF Colistimethate sodium
5. BTS Guideline for bronchiectasis in adults
6. NICE: Bronchiesctasis (non-cystic fibrosis), acute exacerbation: antimicrobial prescribing
7. SPS Purchasing for safety
8. I-neb AAD System User guide


### Stakeholder engagement

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Service Medicine Advice; Medicine Shortage Response Group; NHS England; national clinical experts in cystic fibrosis, respiratory and national patient safety team; Medicine and Healthcare products Regulatory Agency and the Devolved Governments.

### Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.