

Colistimethate sodium/Colistin sulfomethate sodium (Colomycin®) AMBER 0

For Nebulisation in Adult Patients with Non-Cystic Fibrosis Bronchiectasis

Prescribing Information Sheet

As per the British Thoracic Society (BTS) advice when nebulised antibiotic treatment is being used, a multi-disciplinary team should co-ordinate care and provide ongoing support for the patient, while continuing to receive specialist input. Where possible the MDT should include a chest physician, physiotherapist and respiratory nurse. The choice of antibiotic should be guided by antibiotic sensitivity results (where available).¹

Indication

Treatment of adult patients with non-cystic fibrosis bronchiectasis colonised with *Pseudomonas aeruginosa*, who have three or more exacerbations per year requiring antibiotics, or fewer exacerbations that are causing significant morbidity, in whom long term nebulised antibiotic therapy is being considered (off-label indication).

Formulation

It is recommended that brand Colomycin® is prescribed. However, use via nebulisation is not included in the SPC, and it may not be easily obtainable. Promixin® powder and ColiFin® powder for nebulisation are also available but at a greater cost.

Dose

- One million units twice daily or two million units twice daily (as recommended by a specialist).¹ Note: nebulised solutions are typically given over 15minutes.
- Saline Steripoules 0.9%² preservative-free solutions in single dose units are recommended to be prescribed for dissolution of Colomycin® powder². Patients will require 1x 2.5ml amp per colomycin ampule; therefore one box of 20 x 2.5ml amps will last ten days (twice daily administration).
Glass sodium chloride 0.9% ampoules and water for injection ampoules are also available. However, additional consumables are required such as a sharps bin, a syringe and a filter. Therefore, these are not recommended for routine use by patients.
- N.B. Dosing should always be expressed as International Units (IUs) as opposed to being expressed as milligrams which occurs in some non-EU countries.²

Administration

- Colomycin® powder should ideally be dissolved in a single 2.5ml nebuliser of 0.9% Sodium Chloride (NaCl) solution (SPC states 3ml, however Colomycin® is readily soluble in 2-4ml 0.9% NaCl). To do this slowly add the NaCl to the Colomycin® powder and pour into the nebuliser. Alternatively, water for injections may be used. The mixed solution will be slightly hazy. **Do not shake** the solution as it may froth if shaken. The solution may be gently agitated by swirling to aid dissolution and should be allowed to stand for a few minutes after agitation before use.
- Usually, jet or ultrasonic nebulisers are preferred for antibiotic delivery. The instructions of the manufacturers should be followed for the operation and care of the nebuliser and compressor.
- The output from the nebuliser must be vented to the open air, or a filter may be fitted. Nebulisation should take place in a well-ventilated room.²
- To prevent exposure to others, the door of the room should remain closed, and no one else should enter during nebulisation and for 30minutes afterwards (usual practice is to keep the window open in the room during this 30minute period).
- The room Compressors and nebulisers that meet British and European performance and safety standards should be used, and patients/carers must be taught how to use the colistimethate sodium vials and administer the correct dose via the nebuliser.³
- Do not mix with other nebuliser solutions.² Other inhaled drugs should be administered before colistimethate sodium.^{1,3}

Key Interactions

Concomitant use of inhaled colistimethate sodium with other medicines that are nephrotoxic or neurotoxic should only be undertaken with the greatest caution. These include the aminoglycoside antibiotics such as gentamicin, amikacin and tobramycin. There may be an increased risk of nephrotoxicity if given concomitantly with cephalosporin antibiotics.²

Side Effects

Bronchospasm may occur on inhalation of antibiotics.^{1,2} Due to the risk of bronchospasm with inhalation of Colomycin[®], it is recommended the first dose should be administered under supervision in a hospital or clinic setting in secondary care where lung function before and after the initial dose, can be measured. If bronchospasm occurs in a patient not using a bronchodilator, then repeat the test on a separate day using a bronchodilator before the dose of colomycin[®] to assess whether it is safe to continue giving the nebulised colomycin[®] but giving a beta agonist before the antibiotic.^{1,3} The SPC recommends that bronchospasm may be prevented or treated with appropriate use of beta₂-agonists. If troublesome, treatment should be withdrawn.²

Sore throat or mouth has been reported and may be due to *Candida albicans* infection or hypersensitivity. Skin rash may also indicate hypersensitivity if this occurs treatment should be withdrawn.

Monitoring

As per BTS guidance, it is expected that ongoing support will be provided from the respiratory multidisciplinary team. The frequency of patient review and follow up should be communicated to primary care on initiation. Colomycin[®] should be used with caution in renal impairment - it is advisable to assess baseline renal function and to monitor during treatment². Because the frequency of renal monitoring during nebulised colomycin[®] treatment has not been defined in the literature, this should be determined on an individual patient basis by the MDT initiating treatment.

Advice to Patients

- Importance of adherence to the drug regime must be emphasised to patients (results from the key RCT indicate adherence to twice daily nebulisation of colistimethate sodium can be an issue for patients and may result in reduced efficacy of the drug⁴).
- The solution is for single use only, and any remaining solution should be discarded. Patients should return any remaining solution to the supplying pharmacy where appropriate.
- The SPC advises solutions should be used immediately after preparation. If this is not possible, solutions should not be stored for longer than 24hrs in a refrigerator.
- Patients should be informed of potential side effects, including rash and hypersensitivity upon initiation. They should be advised to rinse their mouths with fresh water after inhaling the nebulised solution, to minimise localised exposure.
- Patients should be provided with written information regarding their treatment and use of the equipment from the specialist team when initiating treatment.

For a full list of interactions and side-effects, please consult www.medicines.org.uk/emc or BNF

Version Control. Please access via the LMMG website to ensure the correct version is in use

Version	Date	Amendments Made	Author
1.0	14 th January 2016	First Version Approved	Victoria Birchall/Susan McKernan
1.1	7 th February 2019	New BTS Guideline published and updated SPC	Sharon Andrew
1.2	27 th April 2023	Updated in line with SPC	AGR/PT

References

1. British Thoracic Society. BTS guideline for Bronchiectasis in adults. 2019; Available via <https://www.brit-thoracic.org.uk/quality-improvement/guidelines/bronchiectasis-in-adults> [Accessed online: April 2023].
2. Summary of Product Characteristics. Colomycin 1 million International Units (IU) Powder for solution for injection, infusion or inhalation. Teva UK Ltd. Accessed via: <https://www.medicines.org.uk/emc/product/1094/smpc> [Accessed online: April 2023].
3. Royal Pharmaceutical Society. British National Formulary. Accessed via: www.nice.org.uk/bnf [Accessed online: April 2023].
4. Haworth C.S et al. Inhaled Colistin in Patients with Bronchiectasis and Chronic *Pseudomonas aeruginosa* Infection *Am J Respir Crit Care Med* 2014 189;8:975-982.

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