Nebulised colistimethate Sodium (*Colomycin®*) off-label

Bath and North East Somerset, Swindon and Wiltshire Together

AMBER following specialist initiation: 3-month supply

Background

Colomycin® is licensed for use in patients with cystic fibrosis. Use in non-CF bronchiectasis is outside of the product license but well established and recommended in national guidance from the British Thoracic Society (BTS)[1]. See also NICE guidance NG117[2].

This guidance covers the use of Colomycin for long term prophylaxis in patients with non-CF bronchiectasis who are chronically colonised with *Pseudomonas aeruginosa.*

Treatment aims

Pseudomonas aeruginosa is a pathogen that causes severe lung damage in patients who become colonised. Patients with non-CF bronchiectasis are at risk of significant morbidity and mortality from the damage caused by this pathogen. Nebulised antipseudomonal antibiotic treatment has been shown to slow the rate of respiratory decline and reduce the frequency of infective exacerbations in these patients. Nebulised antibiotics are able to achieve high local concentrations with low systemic absorption and toxicity as opposed to intravenous antibiotics, where there is a high risk of developing adverse effects from systemic absorption. Use of Colomycin® in patients with non-CF bronchiectasis is outside the product license (currently limited to use in CF-bronchiectasis) but use is consistent with BTS recommendations[1].

Secondary care responsibilities/initiation

The specialist will initiate treatment and ensure the first test dose is carried out before a continuous prescription is requested and supply the initial 3 months of treatment.

Secondary care will also provide the nebuliser system/equipment needed and train the patient/carer in the use of the nebulizer, preparation of the medication, and co-ordinate servicing/maintenance of the nebuliser system.

Treatment schedule[1,2,3,4]

Colistimethate comes in vials of either 1 or 2 million units. Colomycin® should be prescribed by brand to reduce risk of supplying alternative products with different licensing and/or at higher cost.

Dose:

- **Eradication** – 1-2 million units nebulised twice a day for 3 months (prescribed/monitored by secondary care)
- **Prophylaxis** – 1-2 million units twice a day

Each vial needs to be diluted with approximately 4 ml of sodium chloride 0.9% (prescribed as solution for injection). Diluents should be prescribed alongside the colistimethate vials.

Before administration of nebulised colistimethate, the patient may administer a bronchodilator such as 2 puffs of a salbutamol inhaler. Advice on use of pre-treatment bronchodilator will be provided by secondary care team.

Nebuliser Systems:

Ombra or Pari Boy compressors and AeroEclipse nebuliser kits are supplies by the hospital. The nebuliser kit is replaced every 6 months for those patients on continuous treatment.

Cautions/contra-indications[3,4]

Coughing and bronchospasm may occur on inhalation of antibiotics. Patient should use a bronchodilator before administration of colistimethate if this occurs.

Bronchial hyper reactivity in response to colistimethate sodium may develop with continued use over time. If signs are shown, treatment should be stopped, and the patient referred back to the specialist.

Colistimethate sodium should be used with extreme caution in patients with myasthenia gravis because of potential for drug induced neuromuscular blockade

Colistimethate sodium should be used with extreme caution in patients with porphyria.

Contra-indications: Hypersensitivity to colistimethate sodium or to polymyxin B.

Side-effects[3,4]

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The most common undesirable effects following nebulisation of colistimethate sodium are coughing and bronchospasm in approximately 10% of patients. Patients may also experience pharyngolaryngeal pain or discomfort, dyspnoea and apnoea. Refer to the SPC or BNF for a full list of adverse effects.

Pregnancy/Breastfeeding

During pregnancy or breast-feeding patients should be managed by secondary care (although nebulised use unlikely to represent safety concern).

Drug interactions[3,4]

Nebulised antibiotics should not be given within an hour of nebulised dornase-alfa (Pulmozyme®).
Drug interactions are unlikely to occur with nebulised colistimethate, however there are reports of serum levels ranging from 0 – 4mg/l (therapeutic) following nebulised colistimethate so the possibility and consequences of systemic absorption should be considered.
Concomitant use of colistimethate with other medicinal products of neurotoxic and/or nephrotoxic potential should be avoided. These include the aminoglycoside antibiotics such as gentamicin, amikacin, netilmicin and tobramycin. There may be an increased risk of nephrotoxicity if given concomitantly with cephalosporin antibiotics.
Neuromuscular blocking drugs and ether should be used with extreme caution in patients receiving colistimethate.

Monitoring

Monitoring is undertaken by the Respiratory team to review initial response and then at least annually. This can take place by telephone or in person and will monitor for adverse reactions, clinical health of the patient and need for further supplies of equipment.

Cost

At current prices, one year's treatment with medicine at the dose is £1314-£2365 (1-2 million units BD) (July DT)

Contact details

Acute trust	Contact details
GWH	Dr Q Jones/Dr M Juniper/Dr R Allcock: 01793 646302 Dr T Onyirioha/Dr C Mackinlay/Dr F Hameed: 01793 646303 Dr M Tinkler/Dr A Kerry: 01793 646146 Respiratory Specialist Nurses 01793 604025
RUH	Respiratory Nurse Specialists 01225 825344 8.30am to 4.30pm Monday to Friday
SFT	SFT Lead Resp. Nurse Specialists: sft.respiratorynurses@nhs.net 01722 429228 or 01722 429220 SFT Consultant Resp. Physicians: sft.admin.respiratory@nhs.net 01722 429228

References

1. British Thoracic Society Guidelines for bronchiectasis in adults. Thorax. 2019 Jan;74(Suppl 1):1-69 available via https://thorax.bmj.com/content/74/Suppl_1/1.long accessed 15/5/25
2. NICE guideline NG117 Bronchiectasis (non-cystic fibrosis), acute exacerbation: antimicrobial prescribing. 18th Dec 2018 accessed 15/5/25
3. Electronic BNF accessed 15/5/25
4. Summary of Product Characteristics for Colomycin 1MU for nebulisation accessed electronically 15/5/25

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