Colistimethate sodium (Colomycin®) for Nebulisation in Patients with Non-Cystic Fibrosis Bronchiectasis INFORMATION FOR PRIMARY CARE

NHS
County Durham and Darlington Area Prescribing Committee

RAG List Status
Colistimethate sodium (Colomycin®) 1 million unit and 2 million unit injection is classified as a GREEN+ drug (requires specialist initiation) by the County Durham & Darlington Area Prescribing Committee, when used in patients with Non-Cystic Fibrosis Bronchiectasis.

Indication
Treatment of patients with non-cystic fibrosis bronchiectasis who are chronically colonised with *Pseudomonas aeruginosa* AND who have three or more exacerbations per year requiring antibiotics or fewer exacerbations that are causing significant morbidity. This is an unlicensed indication but is common practice and recommended in BTS guidance.

The aims of treatment are to improve symptoms, reduce the number of infective exacerbations and to improve health status with long-term use. It may be also used on first acquisition of *Pseudomonas* to attempt to eradicate the infection as part of an extended antibiotic treatment regime with extensive physiotherapy.

When should GPs be asked to prescribe?
GP will only prescribe when treatment has been initiated by a respiratory consultant and remains under their long-term follow-up.

The respiratory team will administer a test dose to check tolerability. They will also educate the patient/carer on how to use the colistimethate sodium vials and administer the correct dose via the nebuliser.

Preparations available
Colistimethate sodium (Colomycin®) 1 million unit and 2 million unit Powder for solution for injection, infusion or inhalation.
1 million IU/vial: Sterile white powder in a 10ml colourless glass vial with a red 'flip-off' cap.
2 million IU/vial: Sterile white powder in a 10ml colourless glass vial with a lilac 'flip-off' cap.

Only the Colomycin® brand should be prescribed. A generic version of colistimethate sodium is available but it is not easily obtainable and use via nebulisation is not listed in the SPC.

Dosage and Administration
1 million units or 2 million units nebulised twice daily (as recommended by specialist).

The plastic cap is flipped open and the foil seal carefully ripped from around the top of the vial to remove it completely. The rubber bung is taken out carefully and sterile Water for injection or sterile Sodium Chloride 0.9% is added to each vial to dissolve the powder as follows:
1 million unit vial: 2ml sterile Water for injection or sterile Sodium Chloride 0.9%
2 million unit vial: 4ml sterile Water for injection or sterile Sodium Chloride 0.9%

Diluent should be provided in plastic amps where possible to negate the use of needles and syringes in dose preparation (e.g. Sodium Chloride 0.9% 2.5ml nebuliser solution or Sodium Chloride 0.9% 2.5ml Steripoules®).

The reconstituted solution will be slightly hazy in colour. Do not shake the solution as it may froth if shaken, but the solution may be gently agitated by swirling to aid dissolution and then left to stand for a few minutes before use. The solution is then poured into the nebuliser.

The solution should be used immediately after preparation and is for single use only. Any remaining solution should be discarded.

Do not mix with other nebuliser solutions. Other inhaled drugs (e.g. bronchodilator) should be administered before colistimethate sodium.

The manufacturer's instructions 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. To prevent exposure to others, the door of the room should remain closed no-one else should enter during nebulisation and for 30 minutes afterwards (usual practice is to keep the window open in the room during this 30 minute period).

Approved: 6.7.2017
Review date: 6.7.2019

Colistimethate sodium (Colomycin®) for Nebulisation in Patients with Non-Cystic Fibrosis Bronchiectasis INFORMATION FOR PRIMARY CARE

NHS
County Durham and Darlington
Area Prescribing Committee

The Respiratory Team at CDDFT is responsible for the supply/maintenance of the nebuliser, and for the supply of equipment required to enable the patient to use the nebuliser (e.g. masks and tubing).

Duration of Treatment
The usual duration of treatment for eradication of first pulmonary colonisation is three months. Eradication is not always successful and should only be attempted once.

Duration may be long-term in patients with chronic colonisation, dependent on patient response to treatment and tolerability. Such patients will remain under follow-up from the respiratory team who will review the patient and advise the GP on when to stop treatment.

Dose Modifications
None required.

Contraindications
- Hypersensitivity to the active substance, polymyxin-B.
- Pregnancy and breast feeding.
- Myasthenia gravis.

Cautions
- Exposure to pregnant carers during nebulisation should be minimised. Advising patients and carer is the responsibility of the respiratory team.
- Use with extreme caution in patients with porphyria.
- Bronchospasm may occur on inhalation of antibiotics. This may be prevented or treated with appropriate use of beta2-agonists. If troublesome, treatment should be withdrawn.
- Renal function monitoring should be performed at the start of treatment and regularly during treatment in all patients.

Drug Interactions
Concomitant use of colistimethate sodium with other medicinal products of neurotoxic and/or nephrotoxic potential should be avoided. 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.

Adverse Effects
Bronchospasm may occur on inhalation of antibiotics. This may be prevented or treated with appropriate use of beta2-agonists. If troublesome, treatment should be withdrawn.
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
Patients should be counselled to report any signs or symptoms of toxicity. The respiratory team will ensure that regular sputum samples, CRP and respiratory function monitoring takes place.

As per BTS Guidance ongoing support for GPs will be provided by the Respiratory Team.

As Colomycin® should be used with caution in renal impairment baseline renal function should be assessed and also monitored during treatment. Because the frequency of renal monitoring during nebulised Colomycin® treatment has not been defined in the literature, it should be determined on an individual basis by the Respiratory Team.

References

- SPC: Colomycin Injection. Updated on eMC 18-May-2016. Forest Laboratories UK Limited (a subsidiary of Actavis PLC).
- British Thoracic Society. Guideline for non-CF Bronchiectasis. 2010; 65: s1. Available at: https://www.brit-thoracic.org.uk/document-library/clinical-information/bronchiectasis/bts-guideline-for-non-cf-bronchiectasis/. Accessed 9/5/2017.

Approved: 6.7.2017
Review date: 6.7.2019