

### Section 1: Heading

**Trust:** North Bristol NHS Trust and University Hospitals Bristol NHS Foundation Trust

**Specialty / Department:** Respiratory Medicine

**Drug:** *nebulised* colistimethate sodium (colistin sulphomethate)

**For the treatment / management of:** Management of chronic respiratory infections / colonisation in adults (not including Cystic fibrosis patients)

### Section 2: Treatment schedule

**Colistimethate sodium** (referred to as colistimethate for remainder of protocol) is available as; a generic preparation, **Colomycin<sup>®</sup>** and **Promixin<sup>®</sup>**  
This shared care protocol specifically refers to the use of **Colomycin<sup>®</sup>** and full prescribing information can be located at [www.medicines.org.uk](http://www.medicines.org.uk)

Colomycin<sup>®</sup> is available as;

- 1 million unit (MU) vial for injection (can also be nebulised)
- 2 million unit (MU) vial for injection (can also be nebulised)

In patients >2yrs of age the recommended dose is 1 – 2 MU dilute with 2 – 4 mL of either water for injection or 0.9% sodium chloride inhaled via the nebuliser twice daily.

No dose adjustment is required in; elderly patients ( $\geq 65$  years), patients with renal impairment or patients with hepatic impairment.

### Section 3: Monitoring

**During treatment with *nebulised* colistimethate no routine monitoring is required.**

Respond to suspected adverse effects (*see Section 4: Side-effects*) as clinically indicated.

### Section 4: Side-effects

See Colomycin<sup>®</sup> SPC section 4.8 - 'Undesirable Effects' at [www.medicines.org.uk](http://www.medicines.org.uk) for full details.

**Bronchospasm** or **cough** may occur on inhalation of colistimethate. This may be prevented or treated with appropriate use of inhaled/nebulised  $\beta_2$ -agonists. But if troublesome or associated with haemoptysis then on-going treatment should be reviewed by an appropriate secondary care specialist. Bronchial hyper-reactivity in response to colistimethate may develop continued use and if suspected should be discussed with the secondary care respiratory team.

**Sore throat or mouth** has been reported and may be due to *Candida albicans* infection (oral thrush) or hypersensitivity. Skin rash may also indicated hypersensitivity.

- Oropharyngeal candidiasis should be treated if indicated.
- If hypersensitivity occurs then treatment should be withdrawn.

### Section 5: Drug interactions

See Colomycin<sup>®</sup> SPC section 4.5 - 'Interactions with other medicinal products and other forms of interaction' at [www.medicines.org.uk](http://www.medicines.org.uk) for full details.

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.

Nebulised antibiotics should not be given within an hour of **dornase-alfa** (Pulmozyme<sup>®</sup>)

### Section 6: Cautions and special recommendations

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

Colistimethate is contraindicated in patients with **myasthenia gravis**.

Colistimethate is contraindicated in patients with hypersensitivity colistimethate (colistin) and/or to **polymyxin B**.

### Section 7: Advice to the patient

The secondary care team will provide information on the appropriate use and care of the nebuliser. This will include advice on;

- Nebulised antibiotics should be used regularly
- The powder in the required number of vials is dissolved, preferably in 2 – 4 mL of either water for injection or 0.9% sodium chloride and poured into the nebuliser. The solution will be slightly hazy and may froth if shaken.
- The solution is for single use only and any remaining solution should be discarded.
- Usually jet or ultrasonic nebulisers are preferred for antibiotic delivery. The instructions of the manufacturers should be followed for operation and care of the nebuliser and compressor.
- Use your reliever inhaler or nebuliser (salbutamol, ipratropium or combination) at least 20 minutes before inhaling the antibiotic.
- If you are carrying out breathing exercises (i.e. Active Cycle of Breathing Technique – ACBT) this should be done after using the reliever but before nebulising colistimethate.
- The nebuliser should be used in conjunction with an exhaust filter to prevent others being exposed to the medication and to prevent a sticky deposit from forming. A new filter should be used for each dose. The procedure should be done in a well-ventilated room.
- After drug administration is completed (which may take up to 20 minutes) rinse your mouth, gargle with water and then spit out. This will reduce the risk of side-effects such as thrush or mouth ulcers.
- After each use the nebuliser should be cleaned as per manufacturer's directions.
- Do not mix colistimethate with other nebuliser solutions (although colistimethate is thought to be compatible with *preservative-free* salbutamol<sup>2</sup>)

### Section 8: Responsibilities for Secondary Care

1. Prescribing responsibility remains with specialist for initial 3 months of treatment.
2. Arrange for an initial test dose to be administered in hospital under appropriate supervision.
3. Initiate therapy after discussion with the patient about treatment options and possible side effects.
4. Arranging the provision of appropriate training for the patient via the nurse specialist.
5. Seek agreement from primary care to continue prescribing under the shared care guideline.
6. Promptly notify primary care to inform them of any dose changes or following treatment discontinuation.
7. Organise on-going review as clinically indicated, typically;
  - Review the patient after 6 months and continue treatment if FEV<sub>1</sub> has improved or there is a reduced rate of FEV<sub>1</sub> decline and the patient is compliant with treatment.
  - On-going review thereafter, at 6 monthly intervals, with continuation of treatment if rate of FEV<sub>1</sub> decline is consistently improved and the patient remains compliant with treatment.
8. U&E's will be assessed at each follow-up.

### Section 9: Responsibilities for Primary Care

1. Assume responsibility for prescribing after initial 3 months of treatment under specialist care.
2. Refer promptly to secondary care if lack of clinical efficacy is suspected or any concerns arise, including suspected adverse drug reactions.
3. Report adverse events to secondary care physician.

### Section 10: Contact details

Name	Organisation	Telephone number	E-mail address	Availability
Respiratory specialist nurses	NBT	0117 323 2247		NBT patients – working hours
Respiratory pharmacist	NBT	Via switchboard 0117 950 5050		NBT patients – working hours
Respiratory on-call Registrar	NBT	Via switchboard 0117 950 5050		NBT patients – 24 hours
Dr Nabil Jarad	UHBristol	0117 342 2620	<a href="mailto:Nabil.Jarad@uhbristol.nhs.uk">Nabil.Jarad@uhbristol.nhs.uk</a>	
Respiratory specialist nurses	UHB	0117 3424101		

### Section 11: Document details

Date prepared:	01/09/2012
Prepared by:	Philip Lloyd Mayers (Pharmacist) on behalf of North Bristol Lung Centre
Date for review:	<b>01/09/2014</b>
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### Section 12: Collaboration

Draft will be circulated to interested parties including; NBT formulary pharmacist and other senior member of the NBT and UBHT pharmacy departments, NBT Respiratory Consultants and Specialist nurses.

### Section 13: References

1. Summary of Product Characteristics: Colistimethate sodium - Colomycin<sup>®</sup>. Forest Laboratories, Inc. July 2012. Accessed via [www.medicines.org.uk](http://www.medicines.org.uk) last updated 08/01/2010.
2. Medicines Q&As. Q&A 100.6 – Which commonly used nebuliser solutions are compatible? UK Medicines Information (UKMi). Prepared 31<sup>st</sup> January 2012.