

Nebulised Colistin – Colistimethate sodium (Colomycin® or Promixin®) for the treatment of Pseudomonas Aeruginosa colonisation and infection in adult patients with non-cf bronchiectasis or bronchial sepsis

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Classification: Shared care protocol

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Issue 2
March 2016

Nebulised Colistin – Colistimethate sodium (Colomycin® or Promixin®) for the treatment of Pseudomonas Aeruginosa colonisation and infection in adult patients with non-cf bronchiectasis or bronchial sepsis

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Who should read this document?

Respiratory Physicians
Advanced Practitioner in Respiratory
Respiratory Specialist Nurses

Key Messages

- Shared Care Policy for the prescribing of nebulised Colistimethate sodium (Colomycin® and Promixin®) in the treatment of lung colonisation or infection with Pseudomonas Aeruginosa in adult patients with non-cf bronchiectasis or bronchial sepsis. Shared care has been defined as the mechanism of sharing patient care between primary and secondary care providers. This document sets out the responsibilities from initial diagnosis to the on-going support.
- Shared care is an agreement between the GP and the consultant. Document has been agreed by SRFT and the patients CCG.
- This shared care document has been developed to facilitate the safe and appropriate prescribing, supply and monitoring of Colistimethate sodium (Colomycin® or Promixin®) in primary and secondary care. It is aimed at all healthcare professionals involved in prescribing, dispensing and monitoring Colistimethate sodium (Colomycin® or Promixin®)
- It has been produced as a result a combination of improved local services for patients with bronchiectasis and new technology available for the delivery of nebulised colistimethate sodium (Promixin®). Reducing the bacterial load can potentially prevent admissions to the hospital by reducing the severity and frequency of infective exacerbations and impact on morbidity and mortality. The new technology can improve enhance concordance and facilitate fast and efficient delivery of the drug into the airways.

What is new in this version?

This is an update with no changes made

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Colistimethate sodium (Colomycin® or Promixin®) is indicated for the treatment by nebulisation of colonisation and infections due to Pseudomonas aeruginosa in patients with bronchiectasis or bronchial sepsis.

Licensed indication

The licensed dose for children >2 years and adults is 1-2 million international units (MIU) every 12 hours.

Therapeutic use and background

Pseudomonas Aeruginosa is a pathogen that causes severe lung damage and subsequent loss of functioning lung in patients who become colonised and then chronically infected. Patients with Bronchiectasis and bronchial sepsis are at risk of significant morbidity and mortality from the damage caused by this pathogen. Nebulised antipseudomonal antibiotic treatment has been shown to improve lung function, 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 high risk of developing adverse effects from systemic absorption.

Colomycin®

Nebulised Colistimethate sodium (Colomycin®) is indicated for chronic pulmonary Pseudomonas Aeruginosa infection in adults with non-cf bronchiectasis or bronchial sepsis. It is also indicated for eradication of first pulmonary colonisation with Pseudomonas Aeruginosa for a period of three weeks – three months (initially with high dose ciprofloxacin)

Colomycin® powder for nebulisation is inhaled using an air compressor and ventstream nebuliser. This equipment is provided by the Respiratory Department at the hospital. The equipment is serviced annually. All the consumables including the filters, ventstream and sidestream nebulisers are replenished by the hospital annually or as required. The hospital provides a helpline within office hours for support with the equipment and consumables.

When Colomycin® is to be initiated by a Consultant Respiratory Physician a letter requesting authorisation for prescribing of Colomycin® powder for nebulisation solution will be sent to the General Practitioner. Once agreed by the General Practitioner and written confirmation sent to the Respiratory team the patient will be invited into the chest clinic for a challenge of the drug. A challenged of one dose of the drug will take place in a controlled safe environment within the hospital outpatient department. This will be supervised by a member of the bronchiectasis team. The first dose for the challenge will be provided by the hospital. If no adverse effects are experienced by the patient they will be provided with all the necessary equipment, consumables; information booklet and contact details for a helpline. The patient will then receive a ten day supply of Colomycin® for home administration. The patient will thereafter request repeat prescriptions for all the necessary therapy from their General Practitioner and redeem their prescription at their local pharmacy.

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The patient will remain under the shared care of the General Practitioner and Respiratory Team team. If any adverse effects are experienced they will be dealt with promptly and alternative treatments will be explored for that individual patient.

Promixin®

Nebulised Colistimethate sodium (Promixin®) is indicated for chronic pulmonary Pseudomonas Aeruginosa infection in adults with non-cf bronchiectasis or bronchial sepsis. It is also indicated for eradication of first pulmonary colonisation with Pseudomonas Aeruginosa for a period of three weeks – three months (initially with high dose ciprofloxacin) Promixin® powder for nebulisation is inhaled using an I-neb® Adaptive Aerosol Delivery (AAD) system, supplied free of charge by the manufacturers of Promixin® (Profile). The I-neb® is a small, battery powered, lightweight and virtually silent drug delivery device designed to significantly reduce the inconvenience of conventional nebuliser/compressor therapy while delivering a precise, reproducible dose of drug. This is particularly useful for patients that need portable therapies for their work environment or travel. The aerosol is created through Vibrating Mesh Technology (VMT), and the dosage of drug is controlled through an AAD Disc and specific metering chambers. The metering chambers can deliver a pre-set volume ranging from 0.25 to 1.4 mL with a residual of about 0.1 ml. The vibrating mesh has a variable power range for the optimization of the aerosol output. I-neb® incorporates an AAD algorithm that pulses medication delivery into 50 to 80 percent of each inspiration, based on a rolling average of the last three breaths. Throughout the treatment, the I-neb® provides continuous feedback to the patient through a liquid crystal display, and upon successful delivery of the treatment, the patient receives audible and tactile feedback.

Dosage regimen

Initial Colonisation with Pseudomonas Aeruginosa should be treated with oral agent if tolerated in the first instance. If eradication is not achieved and the pathogen is sensitive to colistimethate sodium this may be considered as step 2 of the eradication process.

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**Eradication regimen
STEP 1**

CIPROFLOXACIN

750mg tablet BD: 2 weeks (repeat sputum specimen)

(NB If eradication has not been achieved then consider one of the step 2 options)

STEP 2	STEP 2	STEP 2
I.V. anti pseudomonal antibiotics – 2 weeks	Further 4 weeks of Ciprofloxacin 750mg BD Plus 2 MIU Nebulised Colomycin® BD for 3 months Or 1 MIU Nebulised Promixin® BD for 3 months	2 MIU Nebulised Colomycin® BD – 3 months Or 1 MIU Nebulised Promixin® BD for 3 months

Eradication of first growth of Pseudomonas Aeruginosa (step 2)

Colomycin®

Age ≥ 2 years and adults: Colomycin® 2 MIU with 2.5 mls salbutamol and 1.5mls sterile water for injection (4mls in total of diluents), nebulised BD for 3 months. Ciprofloxacin twice daily is co-administered usually for 6 weeks. Dose as outlined below.

Promixin®

Age ≥ 2 years and adults: Promixin® 1 MIU with 1ml of salbutamol or sterile water for injection as diluent, nebulised BD for 3 months. Ciprofloxacin twice daily is co-administered usually for 6 weeks. Dose as outlined below.

Chronic Colonisation (Three or more positive cultures of Pseudomonas Aeruginosa sensitive to colistimethate sodium in a 12 month period) may require long-term therapy with 1 to 2 MIU once or twice daily. Additional parenteral or oral antibiotics may need to be administered to treat acute exacerbations of pulmonary infection.

Prophylaxis

Colomycin® or Promixin® is nebulised once or twice daily on a continual basis.

Availability

Colistimethate Sodium can be obtained on prescription and supplied via the community pharmacist.

Route of administration: Nebulisation

Colomycin®

The dose of Colomycin® administered depends on the individual patient and the frequency and severity of infective exacerbations along with their response to treatments. The patient will administer one nebulised dose of a bronchodilator via the side-stream nebuliser prior to administration of the Colomycin®. Colomycin® is prepared by mixing and diluting the powder with 2mls of water for injection and 2mls of sodium chloride 0.9% (4 mls in total). This should be stated clearly on the prescription. The patient will administer the antibiotic via a vent-stream nebuliser unit that is provided by the hospital. It is important that the patient receives a prescription for 5ml plastic ampoules of each mixing solution in order to be able to effectively draw up and mix the therapy without using a syringe which can be problematic for the patients. The dose should be given once or twice a day. Most patients will prepare Colomycin® 1 MIU twice daily initially then may increase to 2 MIU twice daily on review after 2 months, if indicated.

Promixin®

Promixin® is administered via the I-neb nebuliser, as this is provided free of charge when purchasing the brand specific Promixin® (Colistimethate Sodium). The I-neb® nebuliser requires a disc to be inserted in order for it to function. This disc contains important data that enables the I-neb® to deliver the pre-set dose at the correct power setting. Two discs are provided with each pack of Promixin® vials. After 30 doses of Promixin® the disc is replaced. It is therefore essential that Promixin® is always prescribed in full packs. If the patient is also administering hypertonic saline, the supplying company will provide an additional reservoir for administration via the I-neb®. The second disc is supplied to enable use of other agents via the I-neb device such as hypertonic saline and bronchodilators. A rescue disc is also supplied with the nebuliser in case of loss or damage and further discs can be obtained by calling the helpline.

The dose of Promixin® administered depends on the initial dilution of the 1 MIU vial. Promixin® is prepared by diluting the powder with 1 or 2 mls of water for injection depending on the strength of Promixin® directed by the Specialist. This should be stated clearly on the prescription. The dose should be given once or twice a day. Most patients will prepare Promixin® 1 MIU with 1ml water for injection and nebulise once or twice daily.

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Cost

Colomycin®

Each 1 MIU vial costs £1.80

A month's supply of Colomycin® 1 MIU vials (60) is £108 (excluding diluent 4ml diluent) OD dose

Each 2 MIU vial costs £3.24

A month's supply of Colomycin® 2 MIU vials (60) is £194.40 (excluding diluent 4ml diluent) BD dose

12 months £2332.80

Promixin®

Each 1 MIU vial costs £4.60.

(Equivalent to 2MIU of Colomycin® when nebulised via the I-neb)

A month's supply of Promixin® 1 MIU vials (60) is £276 (excluding diluent 1ml) OD dose

12 months £3312 including equipment, consumables, 24 hour helpline, electronic monitoring programme for effective administration and compliance

This supply will deliver an equivalent dose of 2 MIU when diluted with just 1 ml of solution. The diluents can be sterile water, sodium chloride 0.9% or salbutamol.

Nebulised Colomycin® and Promixin® should be administered after physiotherapy techniques and other inhaled treatments, where indicated. Other inhaled therapies may include agents to reduce the viscoelasticity of sputum and bronchodilators.

The dosage is determined by the severity and type of infection.

The dose may be varied across this range depending on the condition being treated, tolerability of the patient and response to treatment.

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Summary Table 1
Colomycin® (colistimethate sodium)

Drug	Nebuliser	Equivalent dose	Preparation of drug used	Diluents and volume	Volume used in nebuliser
Colomycin® (colistimethate sodium)	Vent-stream	1 MIU BD	1 x 1 MIU vial	2.5ml Salbutamol and 1.5 ml of either sterile water for inj. or sterile 0.9% sodium chloride	4mls four millilitres
		2 MIU BD	1 x 2 MIU vial	2.5ml Salbutamol and 1.5 ml of either sterile water for inj. or sterile 0.9% sodium chloride	4mls four millilitres

Summary Table 2
Colomycin® (colistimethate sodium): for patients intolerant of Salbutamol

Drug	Nebuliser	Equivalent dose	Preparation of drug used	Diluents and Volume	Volume used in nebuliser
Colomycin® (colistimethate sodium)	Vent-stream	1 MIU BD	1 X 1 MIU vial	4ml of either sterile water for inj. or sterile 0.9% sodium chloride	4 mls Four millilitres
		2 MIU BD	1 X 2 MIU vial	4ml of either sterile water for inj. or sterile 0.9% sodium chloride	4 mls Four millilitres

Summary Table 3
Promixin® (colistimethate sodium)

Drug	Nebuliser	Equivalent Dose	Preparation of drug used	Diluents and volume	Volume used in nebuliser
Promixin® (colistimethate sodium)	i-NEB	1 MIU BD	1 x 1 MIU vial	1ml Salbutamol	1mls One millilitres

Summary Table 4
Promixin® (colistimethate sodium): for patients intolerant of Salbutamol

Drug	Nebuliser	Equivalent Dose	Preparation of drug used	Diluents and volume	Volume used in nebuliser
Promixin® (colistimethate sodium)	i-NEB	1 MIU BD	1 X 1 MIU vial	1ml of either sterile water for inj. Or sterile 0.9% sodium chloride	1 ml One millilitres

Agreement of the shared care protocol

When nebulised colistimethate sodium is to be initiated by a Consultant Respiratory Physician a letter requesting agreement to the shared care protocol and ongoing prescribing of the therapy by the General Practitioner will be sent to the surgery for authorisation. Once agreed by the General Practitioner and written confirmation sent to the Bronchiectasis team the patient will be invited into the chest clinic for a challenge of the drug. A challenged of a single dose of the drug will take place in a controlled safe environment within the hospital outpatient department. This will be supervised by a member of the bronchiectasis team. The first dose for the challenge will be provided by the hospital. If no adverse effects are experienced by the patient they will be provided with all the necessary equipment, consumables; information booklet and contact details for a 24 hour helpline. The patient will then receive a ten day supply of Promixin® for home administration. The patient will thereafter request repeat prescriptions for all the necessary therapy from their General Practitioner and redeem their prescription at their local pharmacy. The patient will remain under the shared care of the General Practitioner and Bronchiectasis team. If any adverse effects are experienced they will be dealt with promptly and alternative treatments will be explored for that individual patient.

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Responsibilities of initiating specialist: Consultant/PDNS

- Diagnosis of Pseudomonas Aeruginosa infection or colonisation in patients diagnosed with Bronchiectasis or bronchial sepsis based on a timely and comprehensive assessment.
- Advise the patients General Practitioner (GP) that Pseudomonas Aeruginosa has been isolated and request authorisation to prescribe an initial 10 day course of Promixin®.
- Liaison with the GP to discuss a clear shared care agreement.
- Refer the patient for a challenge of the therapy, if agreed by the GP
- Where agreed by the GP for Promixin to be prescribed contact Profile/Philips Respirationics Pharma to supply the I-neb system, and ensure training of patient/carer in the use of the system
- Supplying the initial sundries where required (needles, syringes, sharps bin).
- Monitor response and indications of adverse drug reactions (ADRs) during the first test dose and the subsequent initial follow up period
- Evaluate evidence of ADR's or any other concerns raised by the GP and discuss alternative treatment options where appropriate.
- Advise GP about possible drug interactions
- Advise the GP if there are any supply issues related to Colomycin® or Promixin®
- In relation to eradication therapy, secondary care will supply the patient with sputum collection pots and advise the patient to send the specimens to their GP for processing in the laboratory at the appropriate time intervals or bring into the chest clinic where appropriate.
- The secondary care bronchiectasis team will follow up the results of sputum cultures after the three months eradication therapy, and relay relevant information to the GP.

Responsibilities of the GP

- Authorisation of the prescribing of Colomycin® or Promixin® powder for nebulised solution and signing of the Shared Care Agreement, where appropriate
- Monitoring the patient's overall health and well being
- Observing the patient for evidence of ADR's or drug intolerance and alerting the Specialist
- Provision of repeat prescriptions of or Colomycin® or Promixin® and any necessary drugs for pre-dosing.
- Arrange supply of diluents and needles/syringes and sharp boxes where required
- Ensuring advice is sought from the secondary care clinician if there is any significant change in the patient's health status
- Reducing and/or stopping treatment in line with secondary care clinicians directive
- For eradication therapy, GP should ensure sputum samples from the patient are sent for processing two weeks after patient has completed the three month eradication therapy period, and send any further samples for processing upon request

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- If the patient lives outside Salford or tests are analysed in laboratories outside Salford the GP will arrange for sputum specimen results to be forwarded to the secondary care bronchiectasis team within an appropriate timeframe

Monitoring

Regular monitoring during treatment is essential to detect adverse reactions at an early stage and patients should be counseled about the risk factors and to report all signs and symptoms of toxicity. Monitoring will be a shared responsibility between the bronchiectasis team in secondary care and the General Practitioner. Monitoring will include sputum specimens, Spirometry, oxygen saturation levels and patient reported symptoms. The GP/PN will arrange for sputum specimens to be collected in line with the individualized management plan. Spirometry and oxygen saturation levels will be assessed at every clinic visit, where indicated. Patients will be provided with a contact number where they can report any adverse effects or indeed query any aspects of this service and their individual care.

Secondary care contact information (Bronchiectasis Team)

Dr Michelle Needham
 Consultant Respiratory Physician
 Lead for Respiratory Medicine
 Salford Royal Hospital
 0161 206 5155/4 (PA, Jane Browne)

Helen Pyne
 Advanced Practitioner
 Respiratory Medicine
 Salford Royal Hospital
 0161 206 0542 (Secretary, Rachael Holme)

Responsibilities of the patient

The patient is responsible for safe administration of the therapy in line with demonstration and instruction provided both verbally in the clinic and written guidance for home reference. The patient must clean and maintain the equipment and seek advice where necessary if equipment fails. The needles must be safely disposed of in the sharps box provided. Any unused drug must be handed to the pharmacist or GP for safe disposal.

The patient must attend their regular clinic appointments with the specialist for ongoing monitoring and management. They should seek medical assessment for their GP if any side effects occur or attend the ED if severe adverse effects noted.

Supporting Information

Summary of Product Characteristics (SPC) Promixin® (Colistimethate sodium); Profile Pharma Limited. Available from e-MC at <http://emc.medicines.org.uk/>

Adverse Effects

The commonest undesirable effects following nebulisation of colistimethate sodium are coughing and bronchospasm (indicated by chest tightness which may be detected by a decrease in FEV1) in approximately 10% of patients.

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Adverse reactions are tabulated below by system organ class and frequency. Frequencies are defined as Very common ($\geq 1/10$): common ($\geq 1/100$ to $< 1/10$): uncommon ($\geq 1/1,000$ to $< 1/100$): rare ($\geq 1/10,000$ to $< 1/1,000$) and very rare ($< 1/10,000$), not known (cannot be estimated from the available data)

Body System	Frequency	Reported adverse reaction
Immune system disorders	Not known	Hypersensitivity reactions such as skin rash
Respiratory, thoracic and mediastinal disorders	Very common	Cough, chest tightness, bronchoconstriction or bronchospasm
General disorders and administration site conditions	Not known	Sore throat and sore mouth

Nebulised Colistimethate Sodium, Colomycin® and Promixin® can potentially causes bronchoconstriction in some patients, which may lead to discontinuation. This may be relieved in some patients by using an inhaled bronchodilator prior to nebulisation or nebulised bronchodilator as diluent for the antibiotic powder.

Contra-indications, Precautions and Warnings

- Colomycin® and Promixin® are contra-indicated in patients with known hypersensitivity to colistimethate sodium.
- Colomycin® and Promixin® are known to reduce the amount of acetylcholine released from the pre-synaptic neuromuscular junction and therefore should not be used in patients with myasthenia gravis
- Use with caution in renal impairment
- Should be used with extreme caution in patients with porphyria

Drug interactions

Nebulised antibiotics should not be given within an hour of dornase-alfa (Pulmozyme®). Concomitant use of inhaled colistimethate sodium with other medications that are nephrotoxic or neurotoxic (e.g. cephalothin sodium, aminoglycosides, non-depolarising muscle relaxants) including those which are administered by the i.v. or i.m. routes should only be undertaken with the greatest caution.

Pregnancy

There is evidence that colistimethate sodium crosses the placenta and consequently there is potential for foetal toxicity is used uring pregnancy. Clinical use suggest probably safe when used by inhalation. Colomycin® and Promixin® should only be given during pregnancy if the benefits outweigh any potential risk. Advising patients and carers is the responsibility of the specialist service.

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Breast feeding

Present in milk but poorly absorbed from gut; manufacturers advise avoid (or use only if potential benefit outweighs risk)

Pharmacokinetic Properties

Absorption

Gastrointestinal absorption is negligible hence the swallowing of colistimethate sodium deposited in the nasopharynx is unlikely to add to the systemic exposure. Absorption following lung administration is influenced by the nebuliser system, aerosol droplet size and disease state of the lungs.

Pharmacokinetics

A study in healthy volunteers, who inhaled colistimethate sodium, demonstrated the C_{max} of polymyxin E1 (the active moiety) varied between 40.0 and 69.9 ng/mL and the AUC varied between 350 and 668 ng/mL/h depending on the nebuliser and the fill volume and concentration, which varied the dose from 0.3 million IU to 2 million IU. The half-life was approximately 5.2 hours. The absolute bioavailability was calculated to vary between 5% and 18% depending on the nebuliser. The AUC following an intravenous dose of 0.5 million IU was 3,352 ng/ml/h and the C_{max} was 1,232 ng/mL.

Standards

This shared care protocol must be adhered to by all medical, nursing, pharmacy and other staff who are involved in the care of patients who are suitable for shared care, as agreed by both the GP and hospital specialist caring for the patient.

Monitoring and review

This shared care protocol will be reviewed on a two yearly basis or in the intervening period if new research is published, or changes to the drug license that means an update is required before the two years have passed.

Explanation of terms & Definitions

i-NEB: Intelligent Nebuliser Adaptive Aerosol Delivery (AAD) System

References and Supporting Documents

References

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Roles and responsibilities

All staff is responsible for checking that their practice complies with the guidance.

The respiratory team is responsible for keeping up-to-date with current research and best practice and disseminating this information.

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Appendices

Appendix 1- GP Shared care agreement letter

Appendix 2 – GP approval for shared care agreement to accompany letter

Appendix 3 – Patient shared care agreement letter

Appendix 4 – GP outcome of drug challenge and ongoing management letter

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Appendix 1

GP Shared care agreement letter

Shared care is an agreement between the GP and the hospital consultant. This letter is a request by the consultant to share the suggested pathway of your patient. If you are unable to agree to the sharing of care and continued prescription of the suggested medication, please make this known to the Consultant within 14 days, stating the nature of your concern.

Your patients respiratory consultant has a recommended nebulised Promixin® antibiotic therapy for your patient. The evidence indicates that this therapy is able to reduce the bacterial load in an attempt to reduce the frequency and severity of infective exacerbations of bronchiectasis and reduce the decline in lung function and improve the patient's quality of life as a result.

Please find enclosed a copy of the Salford Shared Care Agreement for this drug. I would be most grateful if you would complete the approval document and FAX (206 4328) back to the department at your earliest convenience.

If you approve the funding and shared care of this therapy then I will make arrangement for an appointment for your patient to attend the out patients department for a challenge first dose. Your patient will be given a full demonstration of how to make up the drug, have an assessment of their most effective breathing pattern and receive cleaning and equipment maintenance instructions. If they do not experience significant side effects they will be provided with all the necessary equipment, information booklet and 24 hour helpline number.

I have summarised the list of drugs and consumable this patient will require on repeat prescription if there are no significant side effects noted. We will supply the first 10 days of treatment.

Summary of drugs and equipment required from the surgery

Promixin® one million international unit vial (MIU), 1 BD

Salbutamol 2.5mg/2.5ml 1 BD (diluent)

1ml syringe with attached needle (BD insulin syringe available of FP10)

Sharps box

Yours sincerely



Helen Pyne
Advanced Practitioner
Respiratory Medicine



Michelle Needham
Consultant Respiratory Physician
Clinical Lead

Issue 2 March 2016	Nebulised Colistin – Colistimethate sodium (Colomycin® or Promixin®) for the treatment of Pseudomonas Aeruginosa colonisation and infection in adult patients with non-cf bronchiectasis or bronchial sepsis Current Version is held on the Intranet Check with Intranet that this printed copy is the latest issue	Page 16 of 20
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Appendix 2

GP approval for shared care agreement to accompany letter

General Practitioner Agreement to Prescribe Promixin® nebulised antibiotic (Shared Care Agreement attached)

Name	
Hospital Number	
NHS Number	
Date of Birth	

Your patient has significant clinical bronchiectasis. The pathogen isolated within the sputum is pseudomonas, which causes damage to the airway over time. It will reduce the patient's lung function and impact significantly on their quality of life and functionality. In an attempt to reduce the frequency and severity of infective exacerbations we plan to introduce nebulised antibiotic therapy.

We will arrange a challenge of the drug and provision of the necessary, equipment, consumables and access to a 24 hour helpline along with written instructions and advice.

This is an amber cost drug and as such has been presented to the MMG for the hospital and CCG. The drug has been agreed for use with appropriate individuals. We can provide the first 10 days of treatment and would appreciate your agreement to continue thereafter with the prescribing of the therapy, diluent, needle and syringe and sharps box. The patient will be monitored and the treatment discontinued if any side effects occur or indeed if no benefit noted.

Please complete this form and return to Dr Needham's PA, Jane Browne on FAX: 206 4328. If you do not agree to prescribe this therapy we would be most grateful if you could indicate on the form and return it to the department therefore we can utilise the clinic slot and equipment for another patient.

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General Practitioner	
Specialist Respiratory Consultant Physician	Dr Needham
Date of Planned Drug challenge	
General Practitioners signature Date	
Date	
Agree to prescribe Promixin® nebulised antibiotic	YES/NO

If you require any further information please contact Helen Pyne 0161 206 1604 or her secretary Rachael Holme 0161 206 0542

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Appendix 3

Patient shared care agreement letter

Patient Information Letter

Dear (Insert patients name & hospital number),

As you are aware Dr (insert Dr's name) has recommended that you start on treatment with nebulised Promixin® antibiotic therapy

Your GP has agreed to prescribe this treatment. We will arrange an appointment for you to attend the out patient chest clinic for instruction on how to take the treatment and observation of your response to the therapy. A date and time for the appointment will be sent through the post within the next few days. If you are not able to come then please let me know so that someone else can use that time slot in clinic.

You will be given all the necessary equipment and 10 days supply of the treatment from the hospital. Your GP will then provide the treatment on repeat prescription in the usual way.

If you have any queries please contact Helen Pyne 0161 206 1604

Yours sincerely



Michelle Needham
Consultant Respiratory Physican
Clinical Lead



Helen Pyne
Advanced Practioner
Respiratory Medicine

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Appendix 4

GP outcome of drug challenge and ongoing management letter

Dear Dr [insert Doctors name here]

Patient name:[insert Patients name here]

Date of birth: [insert date of birth]

Diagnosis: [insert diagnosis here]

This patient is suitable for treatment with (insert name of drug) for the treatment of (insert name of indication)

This drug has been accepted for Shared Care.

Treatment was started on [insert date started] at a dose of [insert dose]

Summary of drugs and equipment required from the surgery

Promixin® one million international unit vial (MIU), 1 BD

Salbutamol 2.5mg/2.5ml 1 BD (diluent)

1ml syringe with attached needle (BD insulin syringe available of FP10)

Sharps box

The patient was provided with all the necessary equipment, information booklet, 24 helpline number and 10 day supply of Promixin® antibiotic therapy, diluent, needles with syringes and sharps box.

Next review with this department: [insert date]

The patient will not be discharged from out-patient follow-up while taking nebulised Promixin® antibiotic therapy.

Ongoing prescribing will depend on attendance at clinics as requested by the clinicians.

The Consultant or Advanced Practitioner Prescriber is responsible for any dose adjustment.

Thank you.

Yours sincerely



Michelle Needham
Consultant Respiratory Physican
Clinical Lead



Helen Pyne
Advanced Practioner
Respiratory Medicine



Tina Wilding
Respiratory
Specialist Nurse

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