Lincolnshire Primary Care Trust

LINCOLNSHIRE PRIMARY CARE TRUST in association with UNITED LINCOLNSHIRE HOSPITAL TRUST

SHARED CARE GUIDELINE: COLISTIMETHATE SODIUM powder for nebulisation (PROMIXIN) – for the treatment of infections in patients with cystic fibrosis

General Principles

Shared Care Responsibilities:
In its guidelines on responsibility for prescribing (circular EL (91) 127) between hospitals and general practitioners, the Department of Health has advised that legal responsibility for prescribing lies with the doctor who signs the prescription. (*BNF*, 51, March 2006, p. 4)

Aims:
(1) The aim of shared care guidelines is to provide information and/or guidance to GPs and hospital staff relating to the potentially complex implications of sharing patient care for a specific drug between primary and secondary/tertiary care.

(2) Specific shared care guidance should be available for any high cost drug, high-risk drug therapy or device that may be prescribed for a patient following specialist referral. Such guidance will only be produced where shared care is considered an appropriate option.

(3) Each guideline will include a clear statement of the responsibilities of both the GP and the specialist unit within the overall provision of the treatment to the patient.

(4) Shared care guidelines will ensure that the GP has sufficient information available to undertake to prescribe a specialist treatment if s/he so wishes. It is not the intention of these guidelines to insist that GPs prescribe such treatment and any doctor who does not wish to accept clinical or legal responsibility to prescribe such a drug is under no obligation to do so. Nonetheless the development of a shared care guideline will only be undertaken within the context of a broad acceptance between the County-Wide PCT Prescribing Group and secondary/tertiary care that GP prescribing of such a treatment is appropriate within the constraints of formal shared care. Any drug approved for the development of a shared care guideline will automatically be classified as amber on the Lincolnshire Traffic Lights List and, if high-cost, will be supported financially through the High Cost Drugs Reserve. Thus there should be no financial reason why a GP should be deterred from prescribing a high cost drug under a shared care guideline.

Further copies

Further copies of any guidelines in this series are available from PCT Prescribing Advisers.

Date of Issue: October 2006
Review Date: October 2008

Drug Details

Approved Name: Colistimethate sodium

Brand Name: Promixin

Form and Strength: Powder for nebuliser solution. Each vial contains 1 million International Units (1MU) which is approximately equivalent to 80mg of colistimethate sodium

Specialist Responsibilities

The specialist secondary/tertiary care service will assume responsibility for:

1. Initial patient assessment to establish requirement for Promixin®
2. Corresponding with patient's' GP, inviting shared care for the patient. Following acceptance by the GP, the switch to Promixin will proceed.
3. Discussing benefits and potential side effects of treatment with patient
4. Providing information and training for patients in collaboration with Profile Pharma.
5. Continuing clinical assessment of the patient to ensure on-going appropriateness of treatment
6. Communicating any changes to therapy promptly with the patients' GP

GP Responsibilities

The GP will:

1. Notifying the consultant if willing to accept shared care for the patient.
2. Prescribe Promixin® (Promixin® should be supplied in multiples of 30; the boxes must not be split as each box contains an activating disc for the nebuliser).
3. Liase with the Specialist Centre regarding any side-effects reported by the patient to decide the preferred course of action

Referral Criteria

Following initial assessment by the specialist and subsequent acceptance by the GP, the patient will be referred to care of their GP. The specialist centre may provide an initial month of colistimethate sodium (Promixin) therapy on hospital prescription if appropriate.

Licensed Indications

Colisitimethate sodium (Promixin) is indicated for the treatment by nebulisation of colonisation and infections of the lung, due to susceptible Pseudomonas aeruginosa, in patients with cystic fibrosis.

Recommended Dosage and Administration

Children >2 years and adults ; 1 – 2 MIU two or three times daily
The dosage is determined by the severity and type of infection, and the renal function of the patient.
The dose may be varied across this range depending on the condition being treated

Background Pharmacology

Colistin (colistimethate sodium) is a polymyxin B antibiotic indicated for the long-term management of chronic *Pseudomonas aeruginosa* infection of the lung. It is also indicated for three months of eradication therapy following the initial growth of *Pseudomonas aeruginosa* in combination with oral ciprofloxacin. It is given by inhalation of a nebulised solution as an adjunct to standard antibacterial therapy in patients with cystic fibrosis.

Preparations Available

Powder for nebuliser solution. Each vial contains 1 million International Units (1MU) which is approximately equivalent to 80mg of colistimethate sodium
A specific nebuliser, the INeb™ System, is supplied and maintained free of charge by Profile Pharma Ltd. A device is contained within each box of 30 vials which is required to activate the nebuliser, therefore the colistin should always be prescribed by brand as Promixin®.

Adverse Effects

- Bronchospasm on inhalation may be prevented or treated with a selective $beta_2$ agonist or anticholinergic. Any patient describing subsequent bronchoconstriction or wheeze should be advised to discontinue Promixin® and be referred to the Specialist Centre for assessment.
- Hypersensitivity reactions such as skin rash may occur. If suspected, Promixin® should be discontinued and the patient referred to the Specialist Centre.
- Sore mouth and throat, which may be due to hypersensitivity or candidiasis. Patients with these symptoms should be referred to the Specialist Centre.
- Effects more commonly associated with intravenous use of colistin but which may still occur with Promixin® include effects on renal function, and transient sensory disturbances, vertigo, transient facial paraesthesia, vasomotor instability, slurred speech, psychosis, and apnoea.
- Neurotoxicity has been reported in overdose. Neurotoxicity, characterised by dizziness, confusion or visual disturbances have been reported following parenteral administration of colistimethate sodium. If these effects occur patients should be warned against driving or operating machinery.

Drug Interactions

Due to the effects of colistimethate sodium on the release of acetylcholine, non-depolarising muscle relaxants should be used with extreme caution as their effects may be prolonged.

Concomitant used of inhaled colistimethate sodium with other drugs that are nephrotoxic or neurotoxic (e.g. aminoglycosides, non-depolarising muscle relaxants) should only be undertaken with the greatest caution

Contraindications

1. Known hypersensitivity to colistimethate sodium.
2. Myasthenia gravis.
3. Promixin® should only be given during pregnancy if the benefits outweigh any potential risk.
4. Colistimethate sodium is excreted in breast milk; breast feeding is not recommended during therapy.

Cautions

1. Use with caution in renal impairment as colistimethate sodium is renally excreted.
2. Nephrotoxicity or neurotoxicity may rarely occur especially if the recommended dose is exceeded.
3. Use with extreme caution in patients with porphyria.

Monitoring

Baseline:
Physical examination.
Renal function
Respiratory function tests

During therapy:

Patients on Promixin will be reviewed at least every 3 months by the specialist centre. The growth of the organism in the sputum will be monitored and the GP will be notified of any changes.

Indication of Likely Cost of Therapy in Primary Care

Promixin powder for nebulisation (1MIU) – 1 x 30 vials costs £138

Information Given to the Patient

- Promixin® (Profile Pharma Ltd) patient information leaflet.
- Detailed instructions for the I-neb™ AAD® System nebulising equipment.

Contact Details

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References;

British National Formulary 51st ed. March 2006.
Promixin® summary of product characteristics, March 2006.
Promixin® patient information leaflet, June 2005.

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