Adult Cystic Fibrosis Unit
Ninewells Hospital
Dundee

Nebulised Tobramycin (Tobi®) for adult cystic fibrosis patients Shared Care Policy and Information for GPs

August 2004

INTRODUCTION

Lung damage associated with persistent infection by *Pseudomonas aeruginosa* is the major cause of morbidity and mortality in people with cystic fibrosis (CF). Nebulised antipseudomonal antibiotic treatment controls the burden of infection and has been shown to improve lung function, slow the rate of respiratory decline and reduce the frequency of exacerbations of infection in people with CF. This reduces the need for intravenous antibiotic treatment and hospitalisation. In addition, repeated courses of intravenous antibiotics mean that CF patients are at a high risk of developing antibiotic-related toxicity. This can be avoided with nebulised antibiotics, which are able to achieve high local concentrations with low systemic absorption and toxicity. Tobramycin (Tobi®) and colistin (Colomycin®) are the two antibiotics licensed for nebulisation in the United Kingdom. As tobramycin is significantly more expensive that colistin this agent will only be used in patients intolerant of or resistant to nebulised colistin.

SHARED CARE

As outlined in the NHS circular 1992 (Gen 11) a consultant may seek the GPs involvement in prescribing for a patient where there is a shared care agreement. The nature of the management of patients with cystic fibrosis means that it is not possible to completely discharge from secondary to primary care. Rather, a system of shared commitment between the hospital and GP is necessary.

This leaflet provides information on nebulised antibiotic treatment guidelines for the shared care of therapy between the hospital consultant and GP concerned.

INDICATIONS FOR THERAPY

Chronic pulmonary *Pseudomonas aeruginosa* infection in cystic fibrosis patients intolerant of colistin, by inhalation of nebulised solution.

DOSAGE

300mg (one ampoule) every 12 hours for 28 days, courses repeated after 28-day treatment-free interval.

ANNUAL COST

£9,240

ADMINISTRATION

The entire contents of a single ampoule should be placed in the chamber of the nebuliser (Pari LC Plus®) and nebulised to dryness twice daily. Each 28-day period of treatment is repeated after a 28-day treatment-free interval. The nebuliser is supplied by PathoGenesis and the compressor is provided and maintained by the CF Unit, Ninewells.

Tobramycin should not be mixed with other drugs or solutions in the nebuliser as this could lead to adverse structural and / or functional changes.

After each use the nebuliser should be dismantled and cleaned by washing with a mild detergent solution, rinsed thoroughly with tap water and allowed to dry before re-assembly.

AVAILABILITY

Tobi® is prescribable on a GP10 prescription.

Information for Community Pharmacists:
Tobi® is obtainable by faxing an order to PathoGenesis (tel: 020 8580 4036 / fax: 020 8580 4096)

ADVERSE EFFECTS

Voice alteration/hoarseness and tinnitus were reported at a significantly higher frequency in patients receiving nebulised tobramycin compared with placebo. Other side effects that occurred frequently in both tobramycin and placebo groups include cough, pharyngitis, increased sputum, asthenia, rhinitis, dyspnoea, fever, headache, chest pain, sputum discolouration, haemoptysis, anorexia, decreased lung function, asthma, vomiting, abdominal pain, nausea and weight loss.

SHARED CARE RESPONSIBILITIES

Aspects of care for which the hospital consultant is responsible

- assessing suitability of patients for treatment
- initiating treatment
- training of patient in use of nebuliser system
- provision of nebuliser system and replacements
- promoting patient compliance
- providing information and training for GPs
- liaison with GPs to agree shared care
- inform nominated Community Pharmacist and provide information
- assessing and monitoring patient response to treatment
- reporting adverse effects to the CSM

Aspects of care for which the GP is responsible

- prescribing of nebulised antibiotics
- liaison with the hospital consultant regarding any complications of treatment
- reporting adverse drug reactions to the CF Unit
- promoting patient compliance

ADVERSE DRUG REACTION REPORTING

Any adverse drug reaction should be reported to the CF Unit.

WARNINGS

Nebulised tobramycin is contraindicated in patients with a known hypersensitivity to any aminoglycoside.

Caution should be exercised when prescribing nebulised tobramycin to patients with known or suspected renal, auditory, vestibular or neuromuscular dysfunction.

Safety of tobramycin in human pregnancy and lactation has not been established. Please refer to CF Unit for further information.

DRUG INTERACTIONS

There are no known interactions. Solutions for nebulisation must not be mixed in the nebuliser.

PHARMACEUTICAL PRECAUTIONS

Tobramycin for nebulisation should be refrigerated at 2-8°C.

CONTACT POINTS

Ninewells Hosptial, Dundee
Tel: 01382 496457

CF Office/Nurse specialists	**01382 496552**
Dr H C Rodgers (Consultant)	**01382 496552**
Dr J Winter (Consultant)	**01382 496457**
Mrs K Hill (Pharmacist)	**01382 660111** **Bleep 5059**

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This information was prepared by the pharmacist and consultants at the Adult Cystic Fibrosis Unit, Western General Hospital, Edinburgh through liaison with the General Practice Prescribing Committee and the Drug and Therapeutics Committee, Lothian University Hospitals NHS Trust.