Prescribing Information

Promixin 1 million International Units (IU) Powder for Nebuliser Solution
Consult Summary of Product Characteristics before prescribing.

Legal Category: POM
Marketing Authorisation number and basic NHS cost: PL 31654/0008, Pack of 30 vials £204.00
Active Ingredient: colistimethate sodium, 1 million International Units
Uses: Promixin is indicated for the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in adult and paediatric patients with cystic fibrosis.
Dosage and administration: Dose can be adjusted depending on the severity and clinical response. Recommended dose range is: Adults, adolescents and children > 2 years: 1 - 2 million IU two or three times daily (max 6 MIU per day). Children < 2 years: 0.5-1 million IU twice daily (max. 2 MIU per day). Dose adjustment is not considered necessary in older people or patients with renal or hepatic impairment.
Administration is via nebulisation.
Each pack of Promixin contains 30 glass vials, each containing 1 million IU of Promixin Powder for Nebuliser Solution and a Promixin Disc to enable use with the I-neb AAD system.
Contraindications: Contraindicated in patients with known sensitivity to colistimethate sodium or other polymyxins.
Precautions: Nebulisation of colistimethate sodium may induce coughing or bronchospasm. A choking sensation has been reported in some cases. It is advisable to administer the first dose under medical supervision. Pre-dosing with a bronchodilator is recommended. FEV_1 should be evaluated regularly pre and post dosing. Evidence of bronchial hyperreactivity in the presence of a bronchodilator may indicate an allergic response and Promixin should be discontinued.
Colistimethate sodium is renally excreted and is nephrotoxic if high serum concentrations are achieved. Whilst this is unlikely during inhalation therapy, serum concentration estimations are recommended, especially in patients with renal impairment. Nephrotoxicity is usually reversible on discontinuation of therapy.
Neurotoxicity has been associated with high serum concentrations. Dose reduction may relieve symptoms. Concomitant use of inhaled colistimethate sodium with other medications that are nephrotoxic or neurotoxic including those which are administered by the i.v. or i.m. routes should only be undertaken with extreme caution.
Use with extreme caution in patients with porphyria.
Colistimethate sodium acquired resistance in mucoid *Pseudomonas aeruginosa* during clinical use has been reported. Susceptibility testing should be performed on patients who are treated on a long term basis, at regular clinic visits, and whenever a patient experiences an exacerbation.
Colistimethate sodium is known to reduce the presynaptic release of acetylcholine at the neuromuscular junction and should be used in patients with myasthenia gravis with the greatest caution and only if clearly needed.
Safety in human pregnancy has not been established. Colistimethate sodium is excreted in breast milk, breast feeding is not recommended during therapy. There are no data on the effects of colistimethate sodium on human fertility.
Side Effects: Coughing, chest tightness, bronchoconstriction and/or bronchospasm. Sore throat and sore mouth, which may be due to hypersensitivity or superinfection with Candida species. Hypersensitivity reactions including skin rash: if these occur, treatment should be withdrawn.

Further information is available from
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Zambon UK at drugsafetyUK@zambongroup.com or telephone +44(0)800 0288 942