

## **FDA Warning**

### **Colistin in Nebulizer Solution**

**FDA ALERT [6/28/2007]** - FDA is investigating the possible connection between the use of a liquid solution of colistimethate that was premixed for inhalation with a nebulizer and the death of a patient with cystic fibrosis (CF). The drug was prepared by a pharmacy and dispensed as prescribed in premixed unit dose ready-to-use vials. Colistimethate is used to treat *Pseudomonas aeruginosa* infections in the respiratory tract of patients with CF. Colistimethate is FDA approved for intravenous or intramuscular injection; it is not FDA approved for use as a liquid to be inhaled via nebulizer. However, in treating CF patients with *Pseudomonas* infections, colistimethate is often mixed with sterile water to form a solution just prior to inhalation via nebulizer. After mixing with sterile water and a buffer, colistimethate undergoes spontaneous hydrolysis to the bioactive form colistin. A component of colistin, polymyxin E1, is toxic to lung tissue. Premixing colistimethate into an aqueous solution and storing it for longer than 24 hours results in increased concentrations of colistin in solution, increasing the potential for lung toxicity.