Generic Name:
Lucinactant
Trade Name:
Surfaxin
Company:
Discovery Laboratories
Notes:

FDA announced the approval of lucinactant, a new surfactant for the prevention of RDS in premature infants. This is the fifth FDA-approved surfactant to treat RDS in premature infants; the other four agents are beractant (Survanta?Abbott), poractant alpha (Curosurf?Cornerstone Therapeutics), calfactant (Infasurf ?ONY), and colfosceril palmitate (Exosurf?GlaxoSmithKline), which is no longer marketed.

Approval of lucinactant was based on data from a single randomized, active-controlled, multidose study involving 1,294 premature infants. Within 30 minutes of birth, infants in the study received either lucinactant, colfosceril palmitate, or beractant. Lucinactant demonstrated significant improvement in RDS at 24 hours after birth and RDS-related mortality through 2 weeks compared with colfosceril palmitate. The most common adverse events with lucinactant included endotracheal tube reflux, skin paleness, endotracheal tube obstruction, and need for dose interruption.

Medication Monitor Categories:
New Drug Approvals
Use:

Prevention of respiratory distress syndrome (RDS)