Scheduling status **S4**

Proprietary name (and dosage form)
CUROSURF®
Suspension for intratracheal administration 1,5ml and 3 ml (80 mg/ml)

Composition.

Each ml contains 80 mg Poractant alfa

Pharmacological classification.

A 10.2.2 Other (Medicines acting on respiratory system)

Pharmacological action.

Curosurf is a natural surfactant prepared from porcine lungs, mainly containing phospholipids, especially phosphatidylcholine and 1-2 % approximately of surfactant specific hydrophobic low-molecular weight proteins SP-B and SP-C. Its main function is to lower pulmonary surface tension. This action is essential to stabilise alveoli, avoiding collapse at end-expiration so that adequate gas exchange is maintained throughout the ventilatory cycle.

Curosurf remains mainly in the lungs following intratracheal administration. Only traces of surfactant lipids can be found in serum and organs other than the lungs 48 hours after administration.

Indications.

Treatment of preterm babies over 700 g with Respiratory Distress Syndrome (RDS), prophylactic use in premature newborns at risk for RDS.

Contra-indications.

Any specific contra-indications are so far unknown.

Warnings

Dosage and directions for use.

Treatment: Initially, a single intratracheal dose of 100-200 mg/kg (1,25-2,5 ml/kg) is advised. Further doses of 100 mg/kg, administered at 12-hourly intervals, may also be indicated in infants who remain intubated and in whom RDS is considered responsible for their persisting or deteriorating respiratory status.

Prophylaxis: A single dose of 100-200 mg/kg should be administered as soon as possible after birth (preferably within 15 minutes). Further doses of 100 mg/kg can be given 6-12 hours after the first dose and then 12 hours later in babies who have persistent signs of RDS and remain ventilator-dependent.

Administration procedure: Curosurf is available in ready-to-use vials that should be stored in a refrigerator at +2 to + 8 °C. Before use, vials should be warmed to 37 °C and gently turned upside down in order to obtain a uniform suspension.

The suspension should be withdrawn from the vial using a sterile needle and syringe and instilled as a single dose (1,25 or 2,5 ml/kg*)* directly into the lower trachea. Each instillation should be followed by about 1 minute of manual ventilation with an inspired oxygen concentration equivalent to that on the ventilator. Reconnection to the ventilator should initially be made at the same setting as before administration. However, prompt adjustment may then be required according to the clinical status and blood gas analyses. After administration, a close monitoring of arterial blood gases is advisable as an immediate increase in $Pa0_2$ or oxygen saturation is likely to occur. In order to prevent hyperoxia, it is advisable to continuously monitor transcutaneous $Pa0_2$ or oxygen saturation

Side-effects and special precautions.

The baby's general conditions should be stabilised. Correction of acidosis, hypotension, anaemia, hypoglycaemia and hypothermia is also recommended. Babies born following very prolonged rupture of the membranes (greater than 3 weeks) may not show optimal response.

Surfactant therapy may be associated with an increases risk of pulmonary haemorrhage, especially in more premature infants. Therapy should only be given where there are adequate facilities for ventilation and monitoring. Rapid chest expansion and improvement of oxygenation may follow successful treatment and peak ventilatory pressure and inspired oxygen concentration may need to be reduced promptly to avoid the risk of pneumothorax and hyperoxaemia. A transient decrease in brain electrical activity has been reported in neonates given surfactant but its significance is unknown. Haemodynamic changes associated with surfactant therapy may also predispose premature infants to intracranial (periventricular) haemorrhage. Early use of prophylactic surfactant in very low birth-weight infants may be associated with a poorer long-term neurodevelopment outcome.

Known symptoms of overdosage and particulars of its treatment.

There have been no reports of overdosage following the administration of Curosurf, however, in the unlikely event of accidental overdose, and only if there are clear clinical effects on the infant's respiration, ventilation or oxygenation, as much of the suspension as possible should be aspirated and the baby should be managed with supportive treatment, with particular attention to fluid and electrolyte balance.

Identification.

Single dose clear colourless glass vials with rubber stopper and plastic and aluminium caps containing a white to cream-white suspension.

Presentation.

Carton containing one 1,5 ml vial
Carton containing one 3 ml vial

Storage instructions.

Store in a refrigerator at 2 to 8 °C. Protect from light.
Do not use any residual quantity in vial after first aspiration. Unopened, unused vials that have been warmed to room temperature can be returned to refrigerated storage within 24 hours for future use. Do not warm to room temperature (25 ºC ± 2 ºC) and return to refrigerated storage more than once.
Keep out of reach of children.

Registration number

33/10.2.2/0528

Name and business address of applicant.

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