CUROSURF® (poractant alfa) Prescribing Information (ROI)

CUROSURF® (poractant alfa) 120mg and 240mg Endotracheopulmonary Instillation Suspension Prescribing Information.

Please refer to Summary of Product Characteristics (SPC) before prescribing.

Presentation: Single dose vials of 1.5ml or 3.0ml containing either 120mg or 240mg of phospholipid fraction from porcine lung (poractant alfa). **Indications:** For the treatment, including early rescue, of Respiratory Distress Syndrome (RDS) or hyaline membrane disease in newborn babies. Prophylactic use in premature infants requiring intubation for stabilisation at risk from RDS or with evidence of surfactant deficiency. **Dosage and administration:** **Rescue treatment:** Recommended starting dose is 100-200mg/kg (1.25-2.5ml/kg) administered in a single dose ASAP after diagnosing RDS. Additional doses of 100mg/kg (1.25ml/kg) each at about 12-hourly intervals may also be administered if RDS is considered to be the cause of persisting or deteriorating respiratory status of the infants (max total dose of 300-400 mg/kg). **Prophylaxis:** Single dose of 100-200mg/kg administered as soon as possible after birth (preferably within 15 mins). Further doses of 100mg/kg can be given 6-12 hours after first dose and then 12 hours later for persistent signs of RDS and remain ventilator-dependent (max total dose of 300-400mg/kg). Curosurf should only be administered by those trained and experienced in the care, resuscitation and stabilisation of preterm infants. Warm vial to room temp (e.g. holding in the hand for a few mins) and gently turn upside down a few times without shaking to obtain a uniform suspension. Withdraw suspension using sterile needle and syringe. A suitable catheter or tube should be used to instil Curosurf into the lungs. Doses are administered either by: **1) Disconnecting the baby momentarily from the ventilator,** administer 1.25 to 2.5ml/kg of suspension, as a single bolus directly into lower trachea via endotracheal tube. Perform one min of hand-bagging and then reconnect baby to the ventilator at original settings. Further doses (1.25ml/kg) that may be required can be administered in the same manner; **OR 2) Without disconnecting the baby from the ventilator,** administer 1.25 to 2.5ml/kg of the suspension, as a single bolus, directly into the lower trachea by passing a catheter through the suction port and into the endotracheal tube. Further doses (1.25ml/kg) that may be required can be administered in the same manner. After administration, pulmonary compliance can improve rapidly, requiring prompt adjustment of ventilator settings. Rapid adjustments of the inspired oxygen concentration should also be made to avoid hyperoxia. Continuous monitoring of transcutaneous PaO2 or oxygen saturation advisable; **OR 3) Administer through an endotracheal tube in the delivery room before mechanical ventilation has been started** – a bagging technique is used and extubation to CPAP is an option either in the delivery room or later after admission to neonatal unit (INtubation SURfactant Extubation – INSURE); **OR 4) Less Invasive Surfactant Administration with a thin catheter (LISA).** Doses are same as indicated for modalities 1) 2) and 3). In spontaneously breathing preterm infants, a small diameter catheter is placed into the trachea of infants on CPAP ensuring continuous spontaneous breathing with direct visualisation of the vocal cords by laryngoscopy. Instilled by single bolus over 0.5-3 mins. After instillation, tube is immediately removed. CPAP treatment should be continued during the whole procedure. Thin catheters CE marked for this intended use should be used for administration. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** Prior to commencing Curosurf, the infant's general condition should be stabilised. Correction of acidosis, hypotension, anaemia, hypoglycaemia and hypothermia is also recommended. For reflux, stop Curosurf, if necessary adjust ventilator until endotracheal tube clears. If ventilation becomes impaired shortly after dosing, check the endotracheal tube for mucus

plugs. Aspiration of tracheal secretions not recommended for at least 6 hours after administration. In the event of episodes of bradycardia, hypotension and reduced oxygen saturation, administration of Curosurf should be stopped and suitable measures to normalise heart rate should be taken. After administration ,pulmonary compliance (chest expansion) and oxygenation can improve rapidly requiring prompt adjustment of ventilator settings. Improvement in alveolar gas exchange can result in a rapid increase in arterial oxygen, a rapid adjustment to inspired oxygen should be made to avoid hyperoxia. Infants should be monitored for signs of infection and antibiotic therapy given at the earliest signs of infection. Unsatisfactory response to Curosurf or rapid relapse may require considerations of other complications such as patent ductus arteriosus and other lung diseases such as pneumonia before the next dose. Infants born following prolonged rupture of the membranes may not show an optimal response to treatment. After administration, transient depression of cerebro-electrical activity lasting 2-10 minutes has been recorded in one study. With LISA, an increase in frequency of oxygen desaturation, bradycardia and apnoea was seen. Events were of brief duration without consequences and easily managed. If events become serious, stop treatment and treat complications. **Side effects:** Uncommon sepsis, haemorrhage intracranial, pneumothorax. Rare bradycardia, hypotension, bronchopulmonary dysplasia, pulmonary haemorrhage, oxygen saturation decreased. Frequency not known hyperoxia, cyanosis neonatal, apnoea, electroencephalogram abnormal, endotracheal intubation complication. Slight tendency towards increased incidence of patent ductus arteriosus reported in clinical studies. Formation of antibodies against Curosurf has been observed without clinical relevance. In LISA clinical studies, events of frothing at mouth, coughing, choking and sneezing were noted. Increased events of necrotizing enterocolitis and focal interstitial perforation were seen in LISA clinical study but were not statistically significant. See SPC for full details. Additional information available on request**. Legal category:** POM. **Packs:** 120mg/1.5ml single use vial, 240mg/3ml single use vial. **Marketing authorisation (MA) nos:** PA 0584/005/001, PA 0584/005/002. **MA holder:** Chiesi Farmaceutici S.p.A, Italy. **Date of Preparation:** June 2020.

Adverse events should be reported to HPRA Pharmacovigilance, Earlsfort Terrace, IRL, Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. Adverse events should also be reported to Chiesi Limited on 1800 817459 (IE) or PV.UK@Chiesi.com.