ספטמבר 2025

רופא/ה, רוקח/ת נכבד/ה

חברת טבע ישראל בע"מ מודיעה על העדכונים הבאים בעלון <u>לרופא</u> של התכשיר הבא:

CUROSURF® 80 mg/ml קיורוסורף
SUSPENSION FOR ENDOTRACHEOPULMONARY INSTILLATION

Contains: phospholipid fraction from porcine lung 80 mg/ml

עדכונים בעלון לרופא

<u>התוויה כפי שאושרה בתעודת הרישום:</u>

Treatment of Respiratory Distress Syndrome (RDS) in preterm babies.
Prophylactic use in premature infants at high risk for RDS.

<u>ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):</u>

4.2 <u>Posology and method of administration</u>

[…]
or
d. Less Invasive Surfactant Administration with a thin catheter (LISA)
Alternatively, in spontaneously breathing preterm infants Curosurf can also be administered through the Less Invasive Surfactant Administration (LISA) technique using a thin catheter. Doses are the same indicated for modalities under points a) , b) and c). 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. Curosurf is instilled by a single bolus over 0.5-3 minutes.
After Curosurf® instillation, the 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 surfactant administration.

[…]

Special populations

Renal or hepatic failure

The safety and efficacy of CUROSURF in patients with renal or hepatic impairment have not been evaluated.

4.4 Special warnings and precautions for use

[…]

When Curosurf is administered with the LISA technique, an increase in frequency of bradycardia, apnoea and reduced oxygen saturation has been reported. These events are generally of brief duration, without consequences during administration and easily managed. If these events become serious, stop the surfactant treatment and treat the complications.

There is no information available on effects of initial doses other than 100 or 200mg/kg, dosing more frequently than every 12 hours, or administration of CUROSURF starting more than 15 hours after diagnosing RDS.

The administration of CUROSURF to preterm infants with severe hypotension has not been studied.

4.8 Undesirable effects

[…]

LISA technique:

In clinical trials, some transient and mild adverse events, without consequences during administration, were more frequent in the LISA groups than in the standard treatment control groups; in particular: oxygen desaturation (57.4% LISA group vs 26.6% standard group) , apnoea (21.8% vs 12.8%) , bradycardia (11.9% vs 2.8%), froth at the mouth (21.8 vs 2.8%) , coughing (7.9% vs 0.9%), choking (6.9%vs 1.8 %) and sneezing (5% vs 0). This difference between the two groups could be justified by the less frequent use of sedation in the LISA groups vs. standard of care. The majority of these events were easily managed.

During a spontaneous comparative clinical trial (NINSAPP) some cases

of necrotizing enterocolitis requiring surgery (8.4% in the group with LISA method and 3.8% in the group with standard administration- intubation/MV) and focal intestinal perforation requiring surgery (11.2.% in the LISA group and 10.6% in the standard group) were reported, with no statistically significant difference between groups.

These events could be either complications of prematurity or consequences of other treatments used in these preterm babies.

5.1 Pharmacodynamic properties

Clinical efficacy and safety

A spontaneous clinical trial (NINSAPP) has compared the administration of Curosurf with the LISA technique and the standard one (intubation, administration and mechanical ventilation) in two groups of preterms newborns with RDS and gestational age between 23 and 27 weeks (LISA group: N.108 , control group: N. 105). LISA technique was not inferior to the standard one on the primary end-point (survival without bronchopulmonary dysplasia at 36 gestational weeks). On the secondary end-points LISA was superior in increasing survival without major complications and in reducing the frequency of other morbidities associated with prematurity.The need of mechanical ventilation was significantly reduced with LISA.