*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>**

[…]

d. Less Invasive Surfactant Administration with a thin catheter (LISA)

In spontaneously breathing preterm infants CUROSURF can also be administered through a less invasive technique (LISA) whith a thin catheter. Doses are the same indicated for administration methods under points a), b) and c). Keeping the infant breathing spontaneously under CPAP and with a direct view of the vocal cords using a laryngoscope, a small-diameter catheter is placed in the infant's trachea. CUROSURF is instilled by a single bolus over 0.5 – 3 minutes. After CUROSURF instillation, the catheter is immediately removed. CPAP treatment should be continued during the whole procedure.

Thin catheters CE marked for this intended use should be used for the administration of the surfactant.

[…]

**טבע ישראל בע"מ**
www.tevapharm.com I פקס 03-6864944 I טל. 03-6864653 I רחוב התאנה 1, פארק התעשיות חמ"ן ת.ד. 975, שוהם 60850

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 by the LISA technique, an increased frequency of bradycardia, apnoea and reduced oxygen saturation can occur. These events are generally short-lasting, without consequences during administration and easily managed. In the event of their exacerbation, it is necessary to discontinue the therapy in place and treat the ongoing complications.

**4.8 Undesirable effects**

[…]

LISA technique

In clinical trials, some transient and moderate adverse events, without consequences during administration, were more frequent in the group treated with the LISA technique than in the standard treatment control group, in particular: oxygen desaturation (57.4% for the LISA group vs 26.6% for the standard group), apnea (21.8% vs 12.8%), bradycardia (11.9% vs 2.8%), frothing 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 with respect to the 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 treated with LISA method and 3.8% in the group treated 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 the two groups. These events could be either complications of prematurity or consequences of other treatments used in preterm infants.

## 5.1 Pharmacodynamic properties

A spontaneous clinical trial (NINSAPP) has compared the administration of CUROSURF with the LISA technique and the standard technique (intubation, administration and mechanical ventilation) in two groups of preterm 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 at the primary endpoint (survival without bronchopulmonary dysplasia at 36 gestational weeks). On the secondary endpoints LISA was superior in increasing survival without major complications and in reducing the frequency of other morbidities associated with prematurity. The need for mechanical ventilation was significantly reduced in the group treated with LISA technique.