



## Direct Healthcare Professional Communication

Sep 2023

### Lung Surfactants< Product Name>, follow-up the safety and efficacy of the product.

Dear Healthcare Professional,

For the purpose of monitoring the Safety and Efficacy of the Lung Surfactants use in Egypt, a Systemic Collection of the “**Surfactant Use follow-up form**” for each patient in different hospitals has to be filled by HCPs as part of the “**Lung Surfactant Use Registry**”.

**The General Administration for Pharmaceutical Vigilance urges the HCPs to fill the attached form to follow-up the use of surfactant**

- The HCPs should consider to report the data of the neonate candidate to administer the product and make sure to fill the data on: the medications given, Ventilation settings, X-ray observations, and Blood gases results before and after the surfactant injection. While heart rate and oxygen saturation has to be monitored before, within and after injection, and document ex-tubation attempts.

*N.B. The form should be signed, stamped by the hospital stamp in addition to the contact number, to be collected by the company, then to be submitted by the company to the general administration of pharmaceutical vigilance.*

The General Administration for Pharmaceutical Vigilance (EPVC) of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to remind the Healthcare Professionals (HCPs) by the precautions required for the administration of lung surfactants, according to the European Consensus Guidelines on the Management of Respiratory Distress Syndrome 2022:

### Summary:

“Surfactant therapy improves survival and reduces pneumothorax and therefore plays an essential role in management of RDS in preterm infants. Prior to 2013, *prophylactic* surfactant was recommended for the smallest babies as it improved survival in clinical trials from the pre-early (Continuous Positive Airway Pressure) CPAP era.

Intratracheal surfactant administration requires skill and has the potential to cause harm, particularly when ventilating without controlling tidal volumes. Early initiation of CPAP may avoid the harmful effects of intubation and (Mechanical Ventilation) MV during the transitional phase

Since 2013, recommendations have been to only use surfactant in infants showing clinical signs of RDS. The overall aim is to avoid MV if possible while endeavouring to give surfactant as early as possible in the course of RDS, preferably using Less Invasive Surfactant Administration (LISA) methods.





Surfactant must be delivered directly to the trachea, and in most of the early trials, it was given as a bolus through an endotracheal tube, distributed by IPPV followed by a period of weaning ventilation. The Intubation-SURfactant-Extubation “IN-SUR-E” technique, involving surfactant bolus administration followed by brief bag ventilation and rapid extubation without ongoing ventilation, seemed to reduce lung injury. The accepted best method is to use a thin catheter for surfactant administration and avoid “bagging” completely, allowing the infant to maintain spontaneous breathing on CPAP while surfactant is gradually instilled in small aliquots. This method, known as less invasive surfactant administration (LISA).”

**For any inquiries, contact with EPVC on [pv.bio@edaegypt.gov.eg](mailto:pv.bio@edaegypt.gov.eg)**

### Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: [pv.followup@edaegypt.gov.eg](mailto:pv.followup@edaegypt.gov.eg)

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:



Hotline: 15301

### References:

European Consensus Guidelines on the Management of Respiratory Distress Syndrome 2022

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10064400>

### Attachments:

Surfactant Use Follow-up form





Date:.....

Hospital:.....

## Surfactant follow-up form

<b>Patient "initial" and file #</b>		<b>Date of birth:</b>	
<b>Gestational age:</b>		<b>Weight:</b>	
<b>Born in the same hospital?</b>	Yes <input type="checkbox"/> No <input type="checkbox"/> If No, referred from: _____ on date: _____		
<b>Diagnosis of premature infant:</b>	RDS <input type="checkbox"/> others <input type="checkbox"/>		
<b>Comorbidities of neonate:</b>			
<b>Mother`s case description:</b>	<input type="checkbox"/> Single pregnancy <input type="checkbox"/> multiple pregnancy <input type="checkbox"/> hypertension <input type="checkbox"/> Diabetes <input type="checkbox"/> Maternal fever <input type="checkbox"/> UTI <input type="checkbox"/> Premature rupture of membrane >18 hrs		
<b>Administration of prenatal steroids</b>	Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, specify: _____		
<b>Surfactant used:</b>	Alveofact <input type="checkbox"/> Survanta <input type="checkbox"/> Curosurf <input type="checkbox"/>		
<b>Initial Dose:</b>			
<b>Number of doses:</b>	Single dose <input type="checkbox"/> Multiple dose <input type="checkbox"/>		
<b>Date of administration (hours after birth):</b>	<ul style="list-style-type: none"><li>• Date of first dose:</li><li>• Date of second dose (if needed):</li></ul>		
<b>Batch number:</b>			
<b>Storage conditions:</b>			
<b>Preparations / Dilution</b>			

Hospital Stamp

ملحوظة هامة : هذا الاستبيان مُعد من قبل هيئة الدواء المصرية لمتابعة المأمونية والفاعلية الخاصة بال Lung surfactants المستخدمة للأطفال المبتسرين وفي حال وجود اي استفسارات برجاء الرجوع لهيئة الدواء المصرية من خلال الايميل الاتي :: [pv.bio@edaegypt.gov.eg](mailto:pv.bio@edaegypt.gov.eg)

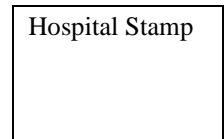


*The following items must be filled Pre-surfactant injection and post-surfactant injection*

Item	Pre-injection	Post-injection
Medications which are given		
Ventilation setting		
X-ray performed		<i>*Within 1 hour of administration</i>
Ultrasound results including Echocardiography		<i>as soon as possible</i>
Blood gases finding:		<i>*Within 1 hour of administration</i>
Any other Lab. tests:		
Lowest reached oxygen saturation during administration		Lowest reached Heart rate during administration
First extubation date:		Final successful extubation date:

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<b>Complications after injection:</b> <i>(if present)</i>	<input type="checkbox"/> Pulmonary hemorrhage <input type="checkbox"/> Pneumothorax <input type="checkbox"/> Others:.....  <input type="checkbox"/> No Complication
<b>Onset of complication:</b>	
<b>Outcome of preterm infant</b>	Survival <input type="checkbox"/> Mortality <input type="checkbox"/> If mortality specify date :

**N.B.** - Make sure to monitor heart rate and Oxygen saturation before, within, and after administration.

- Oxygen saturation measures should be done from right hand.

<b>Further comments:</b>
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Signature: .....

Contact #: .....

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