CUROSURF® 1.5mL SUSPENSION

Consumer Medication Information Leaflet (RiMUP)

(Suspension containing phospholipid fraction from porcine lung(poractant alfa)

What is in this leaflet

1. What Curosurf® is used for

Curosurf® contained active substance, poractant-alfa extracted from pig's lung. It is used to treat or prevent Respiratory Distress Syndrome (RDS) in newborn babies. Most babies are born with a substance in their lungs known as 'surfactant'. This substance lines the lungs and stops them from sticking together and so makes normal breathing possible. Some babies, however, particularly premature babies, do not have enough of this surfactant when they are born, which causes RDS.

Curosurf® is a natural surfactant, which works in the same way as your baby's own surfactant would have done and, therefore, will help your baby to breathe normally until your baby produces his or her own surfactant.

2. How Curosurf® works

Curosurf® is a pulmonary surfactant consisting of natural phospholipids extracted from pig's lung.

It was developed to replace deficiency of endogenous pulmonary surfactant by intratracheal administration of exogenous surfactant.

It acts by lowering surface tension of premature babies lung which is essential to stabilise premature lung and to avoid collapse at end-expiration so that adequate gas exchange is maintained throughout the ventilatory cycle.

3. Before you use Curosurf®

When you must not use it

Do not use Curosurf®:

- If you are allergic (hypersensitive) to the active substance or any excipients of Curosurf®

Before you start to use it

Your baby will only be given Curosurf® if the equipment for ventilation and monitoring babies with Respiratory Distress Syndrome is available.

After being given Curosurf®, your baby will continue to be monitored by the doctor or nurse to ensure that the right amount of oxygen is being given.

During the dosing procedure, occasional episodes of slow heartbeat (bradycardia) and/ or oxygen reduction in the circulation have been reported. If these occur, dosing will be stopped and appropriate measures to relieve the condition will be started. After stabilisation, the dosing procedure will be resumed.

Taking other medicines

No known drug interactions was observed with used of Curosurf®

4. How to use Curosurf®

How much and when to use it

The dosage of Curosurf® varies for each child depending on their body weight.

The usual dose is 100-200 mg Curosurf® per kg body weight. The doctor will calculate the right dose. Usually the first dose will be given as soon as possible after birth (usually within 15 minutes) or as soon as possible after Respiratory Distress Syndrome has been diagnosed (usually within 8 hours of birth).

The dose of Curosurf® will be administered to your baby via a tube already in place in your baby's windpipe. Do not be concerned if your baby is disconnected from its ventilator while Curosurf® is being administered. To make sure that Curosurf® reaches all parts of your baby's lungs, the dose maybe split into smaller doses and your baby's position altered before each part of the dose is given. Further doses at 100mg/kg may be repeated at six to twelve hourly intervals after the first dose. Curosurf® should be warmed to room temperature before administration.

How long to use it

Used of the product is subjected to your baby's response and the doctor judgement.

If you have further questions about your baby's treatment which are not answered by this leaflet, kindly ask your doctor.

If you use too much (overdose)

No overdose case was reported

following administration of Curosurf®

Should it occur, and only if there are clear clinical effects on baby's respiration, ventilation or oxygenation, suspension should be aspirated as much as possible and the baby should be treated with supportive therapies, especially on fluid and electrolyte balance.

5. While you are using Curosurf®

Instructions of administration

Curosurf® is available in ready-to-use vials that should be stored at a temperature between +2 and +8°C.

1. The vial should be warmed to room temperature before use. (i.e: for example by holding it in the hand for a few minutes)
2. Then gently turned upside down a few times, without shaking, to obtain a uniform suspension.
3. The suspension should be withdrawn from the vial by a sterile needle and syringe, following the instruction described in section 6.6 of the SmPC.

Curosurf® can be administered either by :

a. Disconnecting from the ventilator

Disconnect the baby for a moment from the ventilator and directly administered 1.25 to 2.5 ml/kg (100-200 mg/kg) of the suspension, via intratracheal tube, as a single bolus, into the lower part of trachea or via the endotracheal tube, as two halved doses in the main right and left bronchial tubes, respectively. Perform approximately 1 minute of hand-bagging with same percentage of oxygen as before administration, in order to favour uniform distribution and then reconnect the baby to the ventilator and adjust according to the baby clinical response.

OR

b. Without disconnecting from the ventilator

Administer 1.25 to 2.5 ml/kg (100-200 mg/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.

OR

c. INtubation SURfactant Extubation (INSURE)

There is a third option of administration through an endotracheal tube in the delivery room before mechanical ventilation has been started. Doses are the same indicated at points *a)* and *b)*. In this case a bagging technique is used and extubation to *Continuous Positive Airway Pressure (CPAP)* is an option either in the delivery room or later after admission to the neonatal unit (INtubation SURfactant Extubation -INSURE).

OR

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

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.

Things to be careful of

- This product is to be used by and under supervision of healthcare professional only
- Further doses of 100 mg/kg can be given at 6-12 hours after the first dose, and then at 12-hour intervals should RDS appear requiring mechanical ventilation (max. total dose: 300-400 mg/kg).
- Additional dose requirement is subjected to baby response and your doctor's clinical judgement.

6. Side effects

Like all medicines, Curosurf® can be associated with side effects although not everybody gets them. Possible side effects are listed below according to their frequency. If you are not sure what the side effects below are ask your doctor to explain them to you. Uncommon (affecting less than 1 in 100 people)

- Infection
- Bleeding in the brain
- Air in the chest cavity caused by lesions in the lungs

Rare (affecting less than 1 in 1,000 people)

- Slower heart rate
- Low blood pressure
- Chronic lung disease
- Decrease in oxygen around the body

The following side effects have also been reported:

- Increased amount of oxygen in the body
- Blue color skins or gums, caused by too little oxygen
- Stopping of breathing
- Complication with placement of the tubes into the lungs
- Abnormal reading of the brain activity

During the administration of Curosurf® with a thin catheter some mild and transitory adverse events have been seen: bradycardia, apnoea, decreased oxygen saturation, froth at the mouth, coughing, choking and sneezing.

If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Public→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and disposal of Curosurf®

- Keep out of the reach and sight of children.
- Store in a refrigerator at 2°C to 8°C in the original package in order to protect from light. However, before it is given to your baby it will be warmed to room temperature.
- Unopened, unused vials of Curosurf® that have warmed to room temperature can be returned to refrigerated storage within 24 hours for future use. Do not warm to room temperature and return to refrigerated storage more than once.
- Do not use Curosurf® after the expiry date stated on the label after 'Exp'. The expiry date refers to the last day of that month.
- Use each vial once, and then throw away anything that is left over. The hospital will make sure that any unused Curosurf® will be disposed of safely.

8. Product description

What it looks like

It is a sterile suspension and is supplied in single use glass vials containing either 1.5ml (120mg) or 3ml (240mg) of phospholipid fraction from porcine lung. Each ml of sterile suspension contains 80mg of phospholipid fraction from porcine lung.

Ingredients

The active substance is a mixture of fats and proteins which come from pig lung. The other ingredients are sodium chloride, sodium bicarbonate (for pH adjustment) and water for injections. This medicinal product contains less than 1 mmol sodium (23mg) per vial, ie. essentially "sodium free".

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9. Manufacturer and product registration holder

Manufacturer

Chiesi Farmaceutici S.p.A. at 96, Via San Leonardo, 43122 Parma, Italy.

Product registration holder

Pharmaforte (Malaysia) Sdn Bhd
No. 2, Jalan PJU 3/49,
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10. Date of revision

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