



Information Leaflet for Parents or Carers

00284/RE

Curosurf 120mg[®] / vial Endotracheopulmonary Instillation Suspension Curosurf 240mg[®] / vial Endotracheopulmonary Instillation Suspension

Phospholipid fraction from porcine lung

Please read this leaflet carefully as it provides a summary of the information available on your baby's medicine. If you have any questions or are not sure about anything, then please ask the doctor treating your baby.

What is in this leaflet

- 1. What Curosurf is and what it is used for**
- 2. How Curosurf is used**
- 3. Possible side effects**
- 4. How to store Curosurf**
- 5. Contents of the pack and other information**

1. What Curosurf is and what it is used for

Curosurf 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.

Your baby may have other problems as well as RDS which may need other treatments.

2. How Curosurf is used

Dosage:

Your doctor will decide the right dose for your baby, depending on your baby's weight. If your baby is being given Curosurf to prevent Respiratory Distress Syndrome (RDS) it is important that Curosurf is given within 15 minutes after birth. If your baby is being given Curosurf to treat RDS, it is important that Curosurf is given as soon as possible after RDS has been diagnosed. If your baby needs another dose of Curosurf, it will be given 12 hours later. If necessary, a third dose may be given 12 hours after that.

Method of administration:

The doctor or nurse will give Curosurf to your baby in the incubator. They will warm the Curosurf liquid to room temperature, and then using a syringe they will give it to your baby through tubes or thin catheter into the baby's windpipe. They may disconnect your baby from the ventilator for a few minutes to do this.

Please read the back of this leaflet →

3. Possible side effects

All medicines can cause 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 colour of skin 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

If you think any of the above side effects become serious, or noticed any other side effect not mentioned in this leaflet, contact your doctor immediately.

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.

Reporting of side effects

If your baby gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

UK: Yellow Card Scheme at www.mhra.gov.uk/yellowcard .

ROI: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971;

Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

4. How to store Curosurf

- Keep this medicine out of the sight and reach 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 which is stated on the label. 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.

5. Contents of the pack and other information

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

What Curosurf looks like and contents of the pack: It is a sterile suspension and is supplied in single use 5ml 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.

Marketing Authorisation Holder: Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, UK.

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

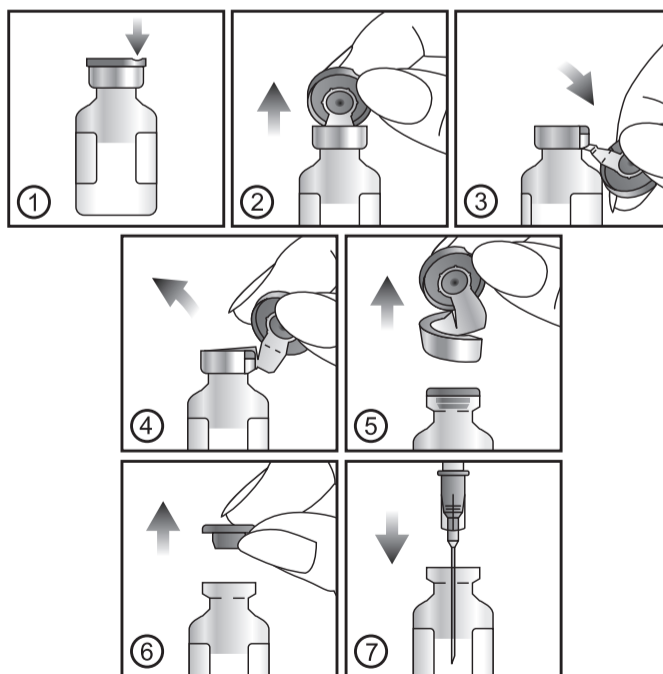
Is this leaflet hard to see or read? Phone for help: 0161 488 5555 (from UK) +44 161 488 5555 (from Ireland).

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How to draw the product:



1. Locate the notch (FLIP UP) on the colored plastic cap.
2. Lift the notch and pull upwards
3. Pull the plastic cap with the aluminium portion downwards
- 4 and 5. Remove the whole ring by pulling off the aluminium wrapper
- 6 and 7. Remove the rubber cap to extract content

Each vial is for single use only. Discard any unused product left in the vial after each administration.

Any unused product or waste material should be disposed of in accordance with local requirements.