

Curosurf[®]

Phospholipid fraction
from porcine lung

 **chiesi**

Information for the parents

The name of your baby's medicine is Curosurf[®]. It is available as a sterile suspension containing either 120 or 240 mg of its active ingredient which is the phospholipid fraction from porcine lung.

What is your baby's medicine?

In addition to the active ingredient Curosurf[®] also contains sodium chloride, sodium bicarbonate and water for injections.

Who is responsible for marketing and manufacturing Curosurf[®]?

The marketing authorisation is held by Trinity Pharmaceuticals Ltd, Tuition House, 27-37 St George's Road Wimbledon, London SW19 4EU.

Curosurf[®] is made and released by Chiesi Farmaceutici S.p.A., 26/A Via Palermo, 43100 Parma, Italy.

Why Curosurf[®]?

Your baby has been given Curosurf[®] because he/she is suffering from, or may be at risk from a condition called respiratory distress syndrome (RDS). Most babies are born with a substance known as surfactant in their lungs. This substance lines the lungs and stops them from sticking together and so makes normal breathing (respiration) possible. Some babies, however, particularly premature babies, are born with a lack of this surfactant, 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.

Note: Curosurf[®] is expected to help in the treatment and prevention of RDS but cannot be expected to help with other problems which are sometimes associated with premature babies.

How many doses will your baby have?

If your baby is at risk from RDS it is important that Curosurf[®] is given either as a preventative treatment as soon as possible after birth or alternatively, as soon as possible after RDS has been diagnosed. Your baby will be/has been given one dose and may receive another two doses at 12 hourly intervals; your doctor will decide how much is necessary for your baby.

How will Curosurf[®] be given to your baby?

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Curosurf[®] is given to your baby whilst it is in the incubator. It is given through tubes into the baby's trachea (windpipe).

Can Curosurf[®] cause side-effects?

All medicines can cause side effects. However, clinical studies on several thousands of newborn babies with RDS did not demonstrate any side effects of surfactant therapy.

This leaflet provides a summary of the information available on your baby's medicine. If you have any questions or are not sure of anything, then please ask your doctor who will have access to additional information.

Storage of the medicine

The medicine must be stored in a refrigerator at +2 to +8 °C, protect from light, until the moment of use.

Do not use any residual quantity in the vial after the first aspiration. Warmed vials should not be returned to the refrigerator.

The medicine should not be used after the date shown on the carton.

The information on this leaflet applies only to Curosurf[®].

Date of preparation: May 2001

Name and address of distributor in Ireland:

Allphar Services Ltd., Pharmaceutical Agents and Distributors, Belgard Road, Tallaght, Dublin 24

Code: CP0001/1

