

What is in this leaflet

This leaflet answers some common questions about CUROSURF. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of your baby receiving CUROSURF against the benefits expected from treatment.

If you have any concerns about your baby being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What CUROSURF is used for

Curosurf is used to treat babies suffering from or at risk of 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 without surfactant and this causes RDS.

Curosurf is a natural surfactant obtained from pigs which works in the same way as human surfactant. It will therefore help your baby to breathe normally until your baby produces their own surfactant.

Curosurf helps to treat and prevent RDS but cannot be expected to help with other problems which are sometimes associated with premature birth.

Curosurf is available only with a doctor's prescription.

How CUROSURF is given

CUROSURF is instilled directly into your baby's trachea or bronchi. CUROSURF is given by a doctor or nurse who is trained and experienced in the care of pre-term babies.

Your baby's doctor will decide what dose should be given and how long your baby will receive CUROSURF. This depends on your baby's weight and other factors, such as how premature your baby is.

Each vial of Curosurf is used once only and the remaining suspension is discarded.

While your baby is being given CUROSURF

The administration of CUROSURF to your baby can affect the ability of your baby's lungs to take up oxygen. Therefore, your baby will be frequently monitored by a nurse or doctor so that oxygen and ventilatory support can be modified as required.

Side effects

Check with your baby's doctor as soon as possible if your baby has any problems while being treated with CUROSURF, even if you do not think the problem is connected with the medicine or is not listed in this leaflet.

Like other medicines, CUROSURF can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor to answer any questions you may have.

Side effects may include:

- bradycardia (a slow heart rate)
- hypotension (low blood pressure)
- coughing
- choking
- sneezing

Some babies may get other side effects while being treated with CUROSURF. Talk to your doctor if you are worried about CUROSURF causing side effects in your baby.

Do not be alarmed by the possible side effects. Your baby may not experience any of them.

Overdosage

As CUROSURF will be given to your baby in a hospital by a suitably trained doctor, the chance of your baby getting an overdosage is very small. However, should this happen, your baby's doctor will know what to do.

Storage

CUROSURF should be stored in the pharmacy or on the ward.

The suspension should be kept in a refrigerator at 2 °C to 8 °C, protected from light. Do not shake the suspension.

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.

Vials are for a single use only.

Product description

What it looks like

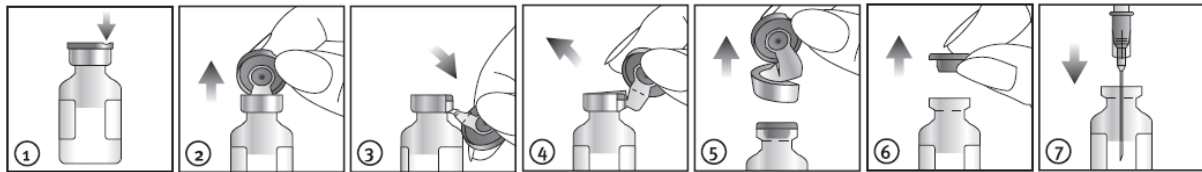
CUROSURF is a white to creamy white suspension which should not be used if there are visible signs of deterioration. It is available in vials of 1.5 or 3 mL which contain 120 mg or 240 mg of the active ingredient poractant alfa.

CUROSURF also contains sodium chloride, sodium bicarbonate and water for injections as excipients.

Instructions for use and other handling

The vial should be warmed to room temperature, before use, and gently turned upside down, without shaking, in order to obtain a homogeneous suspension. The suspension should be withdrawn from the vial using a sterile needle and syringe.

In order to draw the suspension, carefully follow the instructions below:



- 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
- 4) and 5) Remove the whole ring by pulling off the aluminium wrapper
- 6) and 7) Remove the rubber cap to extract content

Sponsor

Chiesi New Zealand Ltd
Bellingham Wallace Ltd
Suite 1, 470 Parnell Road
Parnell
Auckland 1052

Pharmacode 2184559 Curosurf 120 mg
Pharmacode 2184567 Curosurf 240 mg

Date of preparation: May 2026