

CUROSURF®

Intratracheal Suspension

(poractant alfa)

Consumer Medicine Information

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 problem 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 (slow heart rate) and hypotension (low blood pressure). 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. 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.

Date of preparation: September 2021

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, in the original package for protection from light. Do not shake the suspension.

Unopened vials can be warmed to room temperature up to 24 hours before use. CUROSURF should not be warmed to room temperature and returned to the refrigerator more than once. Vials are for a single use only.

Appearance of CUROSURF

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 respectively contain 120 mg or 240 mg of the active ingredient poractant alfa.

CUROSURF also contains sodium chloride as an excipient.

Sponsor

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Australian Registration Numbers:

AUST R 99514 (CUROSURF 120 mg)

AUST R 99515 (CUROSURF 240 mg)