

CUROSURF[®] Intratracheal suspension

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about this medicine, speak to your doctor or pharmacist.

1. Why is my baby having CUROSURF?

CUROSURF contains the active ingredient poractant alfa, a surfactant (surface active agent). CUROSURF is used to treat Respiratory Distress Syndrome (RDS) in premature babies and to prevent it from happening to babies that are at risk of developing this.

For more information, see Section [1. Why is my baby having CUROSURF?](#) in the full CMI.

2. What should I know before my baby has CUROSURF?

Your baby must **not** be given CUROSURF if they are hypersensitive to poractant alfa or any of the ingredients listed at the end of the CMI.

For more information, see Section [2. What should I know before my baby has CUROSURF?](#) in the full CMI.

3. What if my baby is having other medicines?

Tell your doctor about any other medicines you are taking.

More information is in Section [3. What if my baby is having other medicines?](#) in the full CMI.

4. How is CUROSURF given?

CUROSURF is given using a thin tube (catheter) into your baby's trachea (windpipe) where it goes into the bronchi (lungs). It is given by a doctor or nurse trained and experienced in the care of pre-term babies.

More information can be found in Section [4. How is CUROSURF given?](#) in the full CMI.

5. What should I know while my baby is having CUROSURF?

Things you should be aware of	While your baby is being given CUROSURF they may need extra help to make sure they are getting enough oxygen. Your baby will be monitored by a nurse or doctor so that oxygen and ventilation can be adjusted if needed and their airways are clear.
Things you should do	Go to all follow-up appointments after your baby is discharged from hospital so that your doctor can check on your baby's progress.
Storage	CUROSURF will be stored in the hospital pharmacy or on the ward, away from light and moisture, in a refrigerator where the temperature stays between 2°C and 8°C.

For more information, see Section [5. What should I know while my baby is having CUROSURF?](#) in the full CMI.

6. Are there any side effects?

Most side effects, will generally be mild and short-lived, and your baby will be continuously monitored. Side effects may include: slow heart rate (bradycardia), low blood pressure (hypotension), sleeping problems (apnoea), decreased oxygen saturation, froth at the mouth, coughing, choking and sneezing.

For more details about side effects, see Section [6. Are there any side effects?](#) in the full CMI.

CUROSURF[®] Intratracheal suspension

Active ingredient: Poractant alfa

Consumer Medicine Information (CMI)

This leaflet provides important information about using CUROSURF.

Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CUROSURF.

Where to find information in this leaflet:

- [1. Why is my baby having CUROSURF?](#)
- [2. What should I know before my baby has CUROSURF?](#)
- [3. What if my baby is having other medicines?](#)
- [4. How is CUROSURF given?](#)
- [5. What should I know while my baby is having CUROSURF?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why is my baby having CUROSURF?

CUROSURF contains the active ingredient poractant alfa. CUROSURF is a surfactant (surface active agent).

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.

It will be given to your baby by the doctor or nurse in hospital.

2. What should I know before my baby has CUROSURF?

Warnings

Your baby must not be given CUROSURF if:

- they are hypersensitive to poractant alfa or any of the ingredients listed at the end of this leaflet

The doctor or nurse will check the ingredients to make sure your baby can have this medicine.

While having CUROSURF, your baby may be at risk of getting certain side effects. The doctor and nursing staff will watch for them.

See extra information under Section [6. Are there any side effects?](#)

3. What if my baby is having other medicines?

It is not known if CUROSURF will interfere with, or be affected by, other medicines that your baby may be having.

Check with your doctor, nurse or pharmacist if you want to know more about CUROSURF or other medicines your baby may be given.

4. How is CUROSURF given?

How it is given

CUROSURF is given using a thin tube (catheter) into your baby's trachea (windpipe) or bronchi where it goes into the lungs. It is given by a doctor or nurse trained and experienced in the care of pre-term babies.

How much is given

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

Ask your doctor if you want to know more about how much they are giving your baby.

If your baby has too much CUROSURF

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

5. What should I know while my baby is having CUROSURF?

Things you should be aware of

While your baby is being given CUROSURF they may need extra help to make sure they are getting enough oxygen. Your baby will be monitored by a nurse or doctor so that oxygen and ventilation can be adjusted if needed and their airways are clear.

Your baby may also be treated at the same time for other complications of pre-term birth.

Things you should do

Go to all follow-up appointments after your baby is discharged from hospital so that your doctor can check on your baby's progress.

Looking after CUROSURF

CUROSURF:

- will be stored in the hospital pharmacy or on the ward, away from light and moisture in a refrigerator where the temperature stays between 2°C and 8°C.
- Should not be shaken
- may be taken out of the refrigerator and brought up to room temperature over 24 hours before it is given. If not used it can only be returned to the refrigerator on one occasion.
- will be checked before use to see that there are no particles in it

When your baby's medicine will be discarded

Each vial of CUROSURF is used once only and anything left in the vial is discarded.

It will also be thrown away if the expiry date has passed.

6. Are there any side effects?

All medicines can have side effects. If your baby does have any side effects, be aware that your baby will be continuously monitored and treated in hospital and the doctor or nurse will know what to do.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have questions.

Less serious side effects

Less side effects	What to do
Heart: <ul style="list-style-type: none">• low blood pressure (hypotension)• low oxygen which may cause blue colour of skin or gums• slow heart rate (bradycardia) Lungs: <ul style="list-style-type: none">• choking• coughing• sneezing	Tell your doctor or nurse straight away if you notice these side effects. Your doctor or nurse will know what to do.

Serious side effects

Serious side effects	What to do
Hypersensitivity (allergic) reaction* may include: <ul style="list-style-type: none">• rash, itching or hives on the skin, skin redness, swollen face, lips, eyes, tongue or throat or other parts of the body, or trouble breathing	Tell your doctor or nurse straight away if you notice these side effects. Your doctor or nurse will know what to do.

Talk to your doctor if you are worried about CUROSURF causing side effects in your baby.

Reporting side effects

After you have spoken to your doctor, nurse or pharmacist about any side effects your baby may have, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.

What CUROSURF contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• poractant alfa
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sodium chloride• sodium bicarbonate (may be used to adjust the pH (acidity) of the liquid)• water for injections

Your baby must not have this medicine if they are hypersensitive to any of these ingredients.

What CUROSURF looks like

CUROSURF is a white/creamy white suspension in a sterile, clear glass vial. It contains 80 mg poractant alfa per mL of liquid.

There are two sizes:

1.5 mL vial containing 120 mg poractant alfa or

3 mL vial containing 240 mg poractant alfa.

Not all pack sizes may be available.

ARTG Numbers:

AUST R 99514 - CUROSURF 120 mg/ 1.5 mL

AUST R 99515 - CUROSURF 240 mg/ 100 mL

Who distributes CUROSURF

Chiesi Australia Pty Ltd

Level 7, Suite 1, 500 Burke Street,
Melbourne, VIC 3000

Email: medinfo.au@chiesi.com

Website: www.chiesi.com.au

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