Neupedix

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking Neupedix?

Neupedix contains the active ingredient alprostadil. Neupedix is used to temporarily keep the ductus arteriosus open after a child is born.

For more information, see Section 1. Why am I taking Neupedix? in the full CMI.

2. What should I know before I take Neupedix?

Do not use if you have ever had an allergic reaction to Neupedix or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take Neupedix? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Neupedix and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take Neupedix?

- Your child's doctor will decide what dose will be given.
- Neupedix is generally not given for more than 2-3 days at a time. It will be given for the shortest time possible to treat your child properly. Treatment courses may be repeated more than once.
- Treatment will usually start within 4 days after birth.

More instructions can be found in Section 4. How do I take Neupedix? in the full CMI.

5. What should I know while taking Neupedix?

Things you should do	 Tell your doctor if your child is being given any other medicine Tell your doctor or pharmacist if your child has had any medical conditions
Looking after your medicine	 Neupedix will be stored in the hospital refrigerator at 2 to 8°C. If storage is necessary after dilution, store below 25°C for not more than 24 hours. Any solution more than 24 hours old should be discarded Neupedix must not be frozen

For more information, see Section 5. What should I know while taking Neupedix? in the full CMI.

6. Are there any side effects?

Less serious side effects that have been reported include: flushing, swelling, fever, diarrhoea, low potassium in the blood and infections. More serious side effects include: slow or fast heart rate, low blood pressure, fits or convulsions and increased blood clotting. You may need urgent medical attention if you experience any of the following: temporarily stopping breathing and heart attack

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

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Neupedix

Active ingredient(s): alprostadil

Consumer Medicine Information (CMI)

This leaflet provides important information about using Neupedix. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Neupedix.

Where to find information in this leaflet:

- 1. Why am I taking Neupedix?
- 2. What should I know before I take Neupedix?
- 3. What if I am taking other medicines?
- 4. How do I take Neupedix?
- 5. What should I know while taking Neupedix?
- <u>6. Are there any side effects?</u>
- 7. Product details

1. Why am I taking Neupedix?

Neupedix contains the active ingredient alprostadil. Neupedix belongs to a group of medicines called vasodilators.

Neupedix is used to keep a blood vessel called the ductus arteriosis open temporarily after your child is born.

Normally this blood vessel closes soon after birth. In some children who are born with heart defects, this blood vessel needs to be kept open for a longer time so that enough blood can reach the rest of the body.

Once the child's heart defect has been fixed or treated, they will not usually need to be given Neupedix any more, and the blood vessel should close.

Your doctor may prescribe Neupedix for other reasons. Ask your doctor if you have any questions about why Neupedix has been prescribed for your child.

2. What should I know before I take Neupedix?

Warnings

Children with the following medical conditions must not be given Neupedix:

- a blue appearance of the skin, lips and nails due to poor blood flow through the lungs.
- abnormal or unusual blood flow between the lungs and the heart.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if your child:

- takes any medicines for any other condition.
- has any other medical conditions, especially the following:
- 1. history of bleeding tendencies.

2. a breathing problem where the lungs have difficulty holding in air (respiratory distress syndrome).

Your child should only be given Neupedix by qualified medical staff. Treatment will normally take place in a hospital because of the need for hospital facilities and skilled personnel. The possibility of immediate intubation and long-term ventilation must be available.

Neupedix contains alcohol (ethanol). Your doctor will take this into account when deciding to give this medicine to your baby.

During treatment, your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Neupedix and affect how it works.

4. How do I take Neupedix?

How much to take

- Your child's doctor will decide what dose will be given.
- Neupedix is generally not given for more than 2-3 days at a time. It will be given for the shortest time possible to treat your child properly. Treatment courses may be repeated more than once.
- Treatment will usually start within 4 days after birth.

How to take Neupedix

- Neupedix will be given to your child by a doctor, nurse, or other trained person. It is diluted and given by continuous infusion into the bloodstream.
- Your child's blood pressure will be closely monitored while Neupedix is being given.

If you take too much Neupedix

Overdose is unlikely as treatment will be given by trained medical personnel.

Your doctor or pharmacist has information on how to recognize and treat an overdose.

If you think that your child may have been given too much Neupedix, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Neupedix?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Neupedix.

Stay in regular contact with your doctor.

Looking after your medicine

- Neupedix will normally be stored in the hospital where it is stored in the refrigerator (2° C to 8°C).
- Unused ampoules of Neupedix are stored in the refrigerator.
- Neupedix must not be frozen.

After dilution, Neupedix should be used as soon as possible. If storage is necessary after dilution, store below 25°C for not more than 24 hours. Any solution more than 24 hours old should be discarded.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Neupedix, like all other medicines, may cause unwanted side effects. Sometimes they are serious, often they are not.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General disorders: In Flushing Swelling Fever Gastrointestinal disorders: Diarrhoea Blood disorders: Low potassium in the blood Infections	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Heart disorders:	Call your doctor straight
Slow or fast heart rate	away, or go
Low blood pressure	straight to the

Serious side effects	What to do
Heart attack	Emergency
Blood disorders:	Department at your nearest
Increased blood clotting	hospital if you
Breathing disorders:	notice any of these serious
Temporarily stopping breathing	side effects.
Neurological disorders:	
Fits or convulsions	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects your child may experience, 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 Neupedix contains

Active ingredient	Alprostadil
(main ingredient)	
Other ingredients	Ethanol
(inactive ingredients)	

Do not take this medicine if you are allergic to any of these ingredients.

What Neupedix looks like

Neupedix is a sterile, clear, colourless solution for infusion. It is available in a 500 micrograms/mL strength glass ampoule, and each box contains 5 ampoules.

AUST R 446011.

Who distributes Neupedix

Clinect Pty Ltd

120-134 Atlantic Drive, Keysborough

VIC 3173 Australia

Free Call Australia: 1800 899 005

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