

Naloxone Juno and Naloxone Juno Neonatal

Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 using Naloxone Juno and Naloxone Juno Neonatal?

Naloxone Juno and Naloxone Juno Neonatal contains the active ingredient naloxone hydrochloride dihydrate. Naloxone hydrochloride dihydrate is used to reverse the effects of opium-like substances such as morphine, heroin and codeine.

For more information, see Section [1. Why am I using Naloxone Juno and Naloxone Juno Neonatal?](#) in the full CMI.

2. What should I know before I use Naloxone Juno and Naloxone Juno Neonatal?

You should not be given Naloxone Juno and Naloxone Juno Neonatal if you have ever had an allergic reaction to any medicine containing naloxone hydrochloride dihydrate, or any of the ingredients listed at the end of the CMI or any other similar medicines.

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 use Naloxone Juno and Naloxone Juno Neonatal?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Naloxone Juno and Naloxone Juno Neonatal 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 use Naloxone Juno and Naloxone Juno Neonatal?

Naloxone Juno and Naloxone Juno Neonatal must only be given by a doctor or nurse. Your doctor will decide what dose of this medicine you will receive. This depends on your condition and other factors, such as your weight.

More instructions can be found in Section [4. How do I use Naloxone Juno and Naloxone Juno Neonatal?](#) in the full CMI.

5. What should I know while using Naloxone Juno and Naloxone Juno Neonatal?

Things you should do	<ul style="list-style-type: none">• If you become pregnant while being given Naloxone Juno and Naloxone Juno Neonatal, tell your doctor immediately.• Remind any doctor, dentist, pharmacist or nurse you visit that you have been given Naloxone Juno and Naloxone Juno Neonatal• Before surgery, tell the surgeon or anaesthetist that you have been given this medicine.• Tell your doctor if you are about to have any blood tests.• Tell your doctor if you are on a salt restricted diet.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery for at least 24 hours (1 day) after you have been given Naloxone Juno and Naloxone Juno Neonatal.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while you are being given this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Naloxone Juno and Naloxone Juno Neonatal will be stored in the hospital or pharmacy in a cool dry place, protected from light where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Naloxone Juno and Naloxone Juno Neonatal?](#) in the full CMI.

6. Are there any side effects?

Naloxone Juno and Naloxone Juno Neonatal may cause dizziness, headache, nausea, vomiting, pain at the site of the injection, sweating, tremor, increase in heart rate, nervousness, irritability, or restlessness, violent behaviour or agitation, shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin. 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.

Naloxone Juno and Naloxone Juno Neonatal

Active ingredient(s): *Naloxone hydrochloride dihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Naloxone Juno and Naloxone Juno Neonatal naloxone hydrochloride dihydrate (referred to as Naloxone).

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 Naloxone Juno and Naloxone Juno Neonatal.

Where to find information in this leaflet:

[1. Why am I using Naloxone Juno and Naloxone Juno Neonatal?](#)

[2. What should I know before I use Naloxone Juno and Naloxone Juno Neonatal?](#)

[3. What if I am taking other medicines?](#)

[4. How do I use Naloxone Juno and Naloxone Juno Neonatal?](#)

[5. What should I know while using Naloxone Juno and Naloxone Juno Neonatal?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I using Naloxone Juno and Naloxone Juno Neonatal?

Naloxone Juno and Naloxone Juno Neonatal contains the active ingredient naloxone hydrochloride dihydrate.

Naloxone hydrochloride dihydrate belongs to a group of medicines called opioid antagonists.

Naloxone Juno and Naloxone Juno Neonatal is used to reverse the effects of opium-like substances such as morphine, heroin, and codeine.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use Naloxone Juno and Naloxone Juno Neonatal?

Warnings

Do not use Naloxone Juno and Naloxone Juno Neonatal if you:

- are allergic to any medicine containing naloxone hydrochloride dihydrate, or any of the ingredients listed at the end of this leaflet, or any other similar medicines.

Symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have or have had any other medical conditions, especially the following:
 - heart disease
 - lung disease
 - kidney disease
 - liver disease
 - drug addiction (including and addiction to alcohol).

You should not be given Naloxone Juno and Naloxone Juno Neonatal if:

- the solution is discoloured, cloudy, turbid, or a precipitate is present. The injection is normally a clear and colourless solution, practically free from visible particles.

If you are not sure whether you should be given this medicine talk to your doctor.

During treatment, you 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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

If you have not told your doctor about any of the above, tell them before you are given this medicine.

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, herbalist or naturopath.

Some medicines may interfere with Naloxone Juno and Naloxone Juno Neonatal and affect how it works.

These include but are not limited to:

- pain killers

- cough and cold remedies
- alcohol
- heart or blood pressure medications.

These medicines may be affected by Naloxone Juno and Naloxone Juno Neonatal or may affect how well Naloxone Juno and Naloxone Juno Neonatal works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Naloxone Juno and Naloxone Juno Neonatal.

4. How do I use Naloxone Juno and Naloxone Juno Neonatal?

This medicine must only be given by a doctor or a healthcare professional.

How it is given

This medicine can be given:

- as an injection into a muscle (intramuscular)
- just under the skin (subcutaneous) or
- as a slow injection into a vein (intravenous).

How much is given

- Your doctor will decide what dose of this medicine you will receive and how long you will receive it for. This depends on your medical condition and other factors.
- Sometimes only a single dose of this medicine is required.

When to use Naloxone Juno and Naloxone Juno Neonatal

- to reverse the effects of opium-like substances such as morphine, heroin, and codeine.

If you are given too much (overdose)

As this medicine is always given to you in a hospital under the supervision of a doctor, an overdose is unlikely.

Symptoms of an overdose may be the same as side effects but may be more severe. The symptoms of a side effect are listed under [6. Are there any side effects?](#) below.

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.

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

5. What should I know while using Naloxone Juno and Naloxone Juno Neonatal?

Things you should do

- If you are about to be started on any new medicine, tell your doctor, dentist and pharmacist that you have been given Naloxone Juno and Naloxone Juno Neonatal.
- Tell any doctors, dentists and pharmacists who treat you that you have been treated with this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine. It may affect other medicines used during surgery.
- If you are about to have any blood tests, tell your doctor that you have been given this medicine. It may interfere with the results of some tests.
- If you are on a salt restricted diet, tell your doctor that you are taking this medicine. Your diet may need to be changed.

If you feel light-headed, dizzy, or faint when getting out of bed or standing up, get up slowly.

- Standing up slowly, especially when you get up from a bed or a chair, will help your body get used to the change in position and blood pressure. If this problem continues to get worse talk to your doctor.

Call your doctor straight away if you:

- become pregnant while being given Naloxone Juno and Naloxone Juno Neonatal.

Remind any doctor, dentist, pharmacist, or nurse you visit that you have been given Naloxone Juno and Naloxone Juno Neonatal.

Driving or using machines

Do not drive or operate machinery for at least 24 hours (1 day) after you have been given Naloxone Juno and Naloxone Juno Neonatal.

Drinking alcohol

Do not drink alcohol while you are given this medicine.

Looking after your medicine

This medicine will be stored in a hospital. The injection is kept in a cool dry place, protected from the light where the temperature stays below 25 degrees Celsius.

This medicine will only be opened when it is time for you to have the injection.

6. Are there any side effects?

This medicine helps most people reverse the life-threatening opioid overdose, but it may have unwanted side effects in a few people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

Do not be alarmed by the following list of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
Pain at the site of the injection may be experienced. Other side effects may include: Nervous system: <ul style="list-style-type: none"> dizziness, headache Gastrointestinal: <ul style="list-style-type: none"> nausea, vomiting 	Speak to your doctor if you have any of these less serious side effects and they worry you. This list includes the more common side effects of your medicine.

Serious side effects

Serious side effects	What to do
Cardiovascular: <ul style="list-style-type: none"> increase in heart rate Nervous system: <ul style="list-style-type: none"> sweating, tremor, nervousness, restlessness, or irritability, violent behaviour or agitation 	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Very serious side effects

Very serious side effects	What to do
Swelling of the face, lips, tongue or other parts of the body may be experienced. Other side effects may include: Respiratory: <ul style="list-style-type: none"> shortness of breath, wheezing or difficulty breathing Skin: <ul style="list-style-type: none"> rash, itching or hives on the skin 	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. These side effects are very rare.

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 you 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.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What NALOXONE Juno AND NALOXONE JUNO NEONATAL contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> Naloxone hydrochloride dihydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Hydrochloric acid (for pH adjustment) Water for injections

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

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What NALOXONE Juno AND NALOXONE JUNO NEONATAL looks like

The 1 mL ampoule (NALOXONE JUNO) contains 400 micrograms of naloxone hydrochloride (as dihydrate) and Water for Injections to 1 mL. It is available in packs of 1, 5 or 10 ampoules.

The 2 mL ampoule (NALOXONE JUNO NEONATAL) contains 40 micrograms of naloxone hydrochloride (as dihydrate) and Water for Injections to 2 mL. It is available in packs of 1, 5 or 10 ampoules.

Not all pack size is marketed.

Who distributes NALOXONE Juno AND NALOXONE JUNO NEONATAL

Juno Pharmaceuticals Pty Ltd
 15 – 17 Chapel Street
 Cremorne, VIC 3121
www.junopharm.com.au

NALOXONE JUNO AUST R 236005

NALOXONE JUNO NEONATAL AUST R 236003

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