

NALOXONE JUNO

NALOXONE JUNO NEONATAL

Naloxone Hydrochloride Dihydrate Solution for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NALOXONE JUNO and NALOXONE JUNO NEONATAL (referred to as Naloxone). It does not contain all the available information and it does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being treated with this medicine against the benefits it is expected to have for you.

Please read this leaflet carefully and follow the instructions given to you by your doctor and the advice contained in this leaflet.

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

Keep this leaflet.

You may need to read it again.

What NALOXONE JUNO and NALOXONE JUNO NEONATAL is used for

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

Naloxone hydrochloride dihydrate works by reversing the effects of opium-like substances such as morphine, heroin and codeine.

Your doctor may have prescribed this medicine for another reason. Ask your doctor if you have any

questions about why this medicine has been prescribed for you.

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

Before you are given NALOXONE JUNO or NALOXONE JUNO NEONATAL

When NALOXONE JUNO and NALOXONE JUNO NEONATAL must not be given

You should not be given this medicine if you have an allergy to:

- Any medicine containing naloxone hydrochloride dihydrate
- Any of the ingredients listed at the end of this leaflet

Some of the 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.

You should not be given this medicine if the solution is discoloured or cloudy, turbid or a precipitate is present.

The injection is normally a clear and colourless solution, practically free from visible particles.

The doctor or healthcare professional will check to ensure

the medicine is not past its expiry date and has not been tampered with.

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

Before you are given NALOXONE JUNO or NALOXONE JUNO NEONATAL

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any of the following medical conditions:

- Heart disease
- Lung disease
- Kidney disease
- Liver disease
- Drug addiction (including an addition to alcohol)

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding or plan to breastfeed

Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

Tell your doctor about any other medicines you are taking including medicines that you buy without a prescription, in a pharmacy, supermarket or health food shop.

Some medicines may interfere with NALOXONE JUNO or NALOXONE JUNO NEONATAL.

These include but are not limited to:

- Pain killers
- Cough and cold remedies
- Alcohol
- Heart or blood pressure medications

These medicines may be affected or may affect how well NALOXONE JUNO or NALOXONE JUNO NEONATAL works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor has more information on medicines to be careful with or avoid while being given this medicine.

How NALOXONE JUNO and NALOXONE JUNO NEONATAL are given

This medicine must only be given by a doctor or 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.

If you are given too much NALOXONE JUNO or NALOXONE JUNO NEONATAL (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 **Side Effects** below.

Immediately telephone your doctor or Poisons Information Centre for advice (in Australia telephone 13 11 26, in New Zealand telephone 0800 POISON (0800 764 766) or go to Accident & Emergency at your nearest hospital if you think you or anyone else has been given too much of this medicine.

While you being treated with NALOXONE JUNO or NALOXONE JUNO NEONATAL

Things you must do

If you are about to be started on any new medicine, remind your doctor and healthcare professional that you have been given NALOXONE JUNO or NALOXONE JUNO NEONATAL.

Tell any other 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 become pregnant while being given this medicine, tell your doctor immediately.

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.

Things to be careful of

Do not drive or operate machinery after you have been given NALOXONE JUNO or NALOXONE JUNO NEONATAL for at least 24 hours (1 day).

Do not drink alcohol while you are being given this medicine.

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 or gets worse, talk to your doctor.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given this medicine.

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. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Ask your doctor to answer any questions you may have.

Ask your doctor or nurse if you notice any of the following and they worry you.

- Dizziness
- Headache
- Nausea
- Vomiting
- Pain at the site of injection

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- Sweating
- Tremor
- Increased heart rate
- Nervousness or restlessness
- Irritability
- Violent behavior or agitation

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor or healthcare professional immediately:

- 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

The above list includes very serious side effects. You may need urgent medical attention or further hospitalization. These side effects are very rare.

Tell your doctor or healthcare professional if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After treatment with NALOXONE JUNO and NALOXONE JUNO NEONATAL

Storage

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.

Product Description

What it looks like

NALOXONE JUNO and NALOXONE JUNO NEONATAL Solution for Injection is a clear and colourless solution. It should not be given if there are any crystals or particles visible in the solution.

Ingredients

Active ingredient: Naloxone hydrochloride dihydrate.

The inactive ingredients are hydrochloric acid (for pH adjustment) and water for injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine, alcohol, dyes or preservatives

The 1 mL ampoule (NALOXONE JUNO) contains 400 micrograms of naloxone hydrochloride 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 dihydrate and Water for Injections to 2 mL. It is available in packs of 1, 5 or 10 ampoules.

If you want to know more

If you have any questions about your treatment with this medicine, ask your doctor or pharmacist.

Supplier

Juno Pharmaceuticals Pty Ltd
Level 2, 6 Bond Street
South Yarra
VIC - 3141
Australia

NALOXONE JUNO AUST R 236005

NALOXONE JUNO NEONATAL AUST R 236003

This leaflet was prepared in August 2016.