

# NALOXONE SXP

## 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 being given NALOXONE SXP?

NALOXONE SXP contains the active ingredient naloxone hydrochloride dihydrate. NALOXONE SXP is used to reverse the effect of opium-like substances such as morphine, heroin and codeine.

For more information, see Section [1. Why am I being given NALOXONE SXP?](#) in the full CMI.

### 2. What should I know before I am given NALOXONE SXP?

You should not be given NALOXONE SXP if you have ever had an allergic reaction to this medicine 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 am given NALOXONE SXP?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with NALOXONE SXP 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 am I given NALOXONE SXP?

- NALOXONE SXP Injection is given as an injection into a muscle, under the skin or as a slow injection into a vein.
- NALOXONE SXP Injection should only be given by a doctor or nurse. Your doctor will decide on the dose.
- In emergency situations, NALOXONE SXP may be given by paramedical staff, such as an ambulance attendant.
- More instructions can be found in Section [4. How am I given NALOXONE SXP?](#) in the full CMI.

### 5. What should I know while being given NALOXONE SXP?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist that you visit that you have been given NALOXONE SXP.</li><li>• Tell your doctor if you are pregnant, intending to become pregnant or are breastfeeding.</li><li>• Tell your doctor if you have heart disease, lung disease, drug addiction, kidney disease or liver disease.</li><li>• If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly after being given NALOXONE SXP.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how NALOXONE SXP Injection affects you. NALOXONE SXP may cause dizziness or light-headedness in some people and therefore driving or operating machinery may be dangerous.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Be careful when drinking alcohol while you are being given this medicine, as it may cause light-headedness or dizziness in some people.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• NALOXONE SXP Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while being given NALOXONE SXP?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include nausea or vomiting, headache, light-headedness or dizziness, high or low blood pressure.

Signs of drug withdrawal are serious and may include sweating, increased heart rate, tremor, rapid breathing, paranoia, self-harm, seizures, violent behaviour, delirium, nervousness, restlessness, irritability, excitement, agitation and tingling in the hands or feet. Other serious side effects are flaking skin or fluid in the lungs.

Symptoms of an allergic reaction may be serious and they include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, and 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 SXP

Active ingredient: naloxone hydrochloride dihydrate

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I being given NALOXONE SXP?](#)
- [2. What should I know before I am given NALOXONE SXP?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given NALOXONE SXP?](#)
- [5. What should I know while being given NALOXONE SXP?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I being given NALOXONE SXP?

**NALOXONE SXP contains the active ingredient naloxone hydrochloride dihydrate.** NALOXONE SXP is a medicine which, when injected, reverses the effect of opium-like substances such as morphine, heroin and codeine.

**NALOXONE SXP is used after surgical operations when powerful pain killers which have been given during an operation and are no longer required.**

As NALOXONE SXP acts very quickly, within one or two minutes when injected into a vein, it can also be used as a lifesaving measure in those people who have received an overdose of an opioid-like drug.

### 2. What should I know before I am given NALOXONE SXP?

#### Warnings

**You must not be given NALOXONE SXP if:**

- you are allergic to naloxone, or any of the ingredients listed at the end of this leaflet.

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

Symptoms of an allergic reaction to naloxone 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.

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition
- you allergies to any other medicines, or other substances, such as foods, preservatives or dyes.

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. Your doctor will discuss the possible risks and benefits of being given NALOXONE SXP Injection during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the possible risks and benefits of being given NALOXONE SXP Injection during breast-feeding. It is not known whether passes into breast milk.

**Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:**

- heart disease
- lung disease
- drug addiction
- kidney disease
- liver disease.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given NALOXONE SXP Injection.

### 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 NALOXONE SXP and affect how it works.**

These include:

- pain killers
- cough and cold remedies
- heart or blood pressure medication

These medicines maybe affected by naloxone or may affect how well it works. You may need different amounts of your medicine or you may need to take or use different medicines. Your doctor or pharmacist will advise you.

**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 SXP.**

## 4. How am I given NALOXONE SXP?

### How much is given

- Your doctor will decide what dose you will receive.
- Your dose will depend on your condition and other factors.
- NALOXONE SXP Injection is usually given as a single dose but may be repeated if necessary.

### How it is given

NALOXONE SXP Injection is given either:

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

Injection into a vein is the most common site of administration in an emergency situation.

NALOXONE SXP Injection should only be given by a doctor or nurse. In emergency situations it may be given by paramedical staff, such as an ambulance attendant.

### If you are given too much NALOXONE SXP

If you think that you have been given too much NALOXONE SXP, 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.

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

NALOXONE SXP Injection is known to be safe in very large doses in animals.

However, severe withdrawal symptoms can be produced in drug addicts if too much naloxone is used.

As NALOXONE SXP Injection is given by a medical professional, they will monitor for symptoms of overdose.

## 5. What should I know while being given NALOXONE SXP?

### Things you should do

**Remind any doctor, dentist or pharmacist you visit that you have been given NALOXONE SXP Injection.**

**Tell your doctor if you are pregnant, intending to become pregnant or are breastfeeding.**

**Tell your doctor if you have heart disease, lung disease, drug addiction, kidney disease or liver disease.**

**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 bed or chairs, will help your body get used to the change in position and blood pressure.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how NALOXONE SXP Injection affects you.**

NALOXONE SXP may cause dizziness in some people.

### Drinking alcohol

**Be careful when drinking alcohol while you are taking this medicine.**

This medicine may cause light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### Looking after your medicine

NALOXONE SXP Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

### Getting rid of any unwanted medicine

NALOXONE SXP Injection will be disposed of by a health care professional.

## 6. Are there any side effects?

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.

**Abrupt reversal of the effects of opium-like substances may result in withdrawal symptoms.**

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• nausea</li><li>• vomiting</li><li>• light-headedness</li><li>• dizziness</li><li>• headache</li><li>• high or low blood pressure</li></ul>	<b>Speak to your doctor if you have any of these side effects and they worry you.</b>

These are the more common side effects of naloxone. Mostly these are mild and short-lived.

You should tell your doctor if these symptoms worry you, as they may be signs of drug withdrawal.

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>fluid in the lungs</li><li>flaking skin</li></ul> Symptoms of drug withdrawal include: <ul style="list-style-type: none"><li>paranoia</li><li>self-harm</li><li>seizures</li><li>delirium</li><li>violent behaviour or agitation</li><li>irritability or excitement.</li><li>tingling in the hands or feet</li><li>nervousness or restlessness</li><li>sweating</li><li>increased heart rate</li><li>tremor</li><li>rapid breathing</li></ul> Symptoms of an allergic reaction include: <ul style="list-style-type: none"><li>shortness of breath</li><li>wheezing or difficulty breathing</li><li>swelling of the face, lips, tongue or other parts of the body</li><li>rash, itching or hives on the skin.</li></ul>	<b>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.</b>

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

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

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](http://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 SXP contains

<b>Active ingredient (main ingredient)</b>	naloxone hydrochloride (as dihydrate)
<b>Other ingredients (inactive ingredients)</b>	hydrochloric acid sodium chloride water for Injections sodium edetate

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

NALOXONE SXP Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

NALOXONE SXP Injection is not addictive.

### What NALOXONE SXP looks like

NALOXONE SXP Injection is a clear colourless solution.

It should not be given if there are any crystals or particles visible in the solution.

NALOXONE SXP Injection is available in the following strengths and packs:

400 microgram/mL,

5 x 2 mL ampoules

10 x 2 mL ampoules

(AUST R 315388)

### Who distributes NALOXONE SXP

Southern XP Pty Ltd

Unit 5/118 Church Street

Hawthorn VIC 3122

#### Sponsor:

Southern XP IP Pty Ltd

Unit 5/118 Church Street

Hawthorn, 3122, Victoria

Australia

This leaflet was prepared in June 2022.