

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using SUBLOCADE?

SUBLOCADE contains the active ingredient buprenorphine. SUBLOCADE is used as part of medical, social and psychological treatment program for patients dependent on opioids. For more information, see Section [1. Why am I using SUBLOCADE?](#) in the full CMI.

2. What should I know before I use SUBLOCADE?

Do not use if you have ever had an allergic reaction to SUBLOCADE 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. Tell your doctor if you have or have had any of the following medical conditions: kidney disease, liver problems, breathing problems, problems with excess alcohol use or history of seizures.

For more information, see Section [2. What should I know before I use SUBLOCADE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with SUBLOCADE 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 SUBLOCADE?

- SUBLOCADE must be administered only by your doctor or healthcare professional.
- The recommended first two doses of SUBLOCADE are 300 mg. The subsequent dosing will be selected by your doctor based on clinical assessment of your condition.

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

5. What should I know while using SUBLOCADE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are using SUBLOCADE• If you are going to have surgery, tell the surgeon or anaesthetist that you are using SUBLOCADE• Tell your family or friends that, in the event of emergency, they should inform the treating healthcare provider or Emergency Room staff that you are being treated with SUBLOCADE
Things you should not do	<ul style="list-style-type: none">• Do not rub or massage the injection site and be aware of placement of any restrictive clothing such as belts, waistbands or sleeves• Do not attempt to tamper with the medicine once given by your healthcare provider
Driving or using machines	<ul style="list-style-type: none">• SUBLOCADE may cause drowsiness which may be made worse if you drink alcohol or take sedatives or anti-anxiety medications• Be careful driving or operating machinery until you know how SUBLOCADE affects you
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol or take medicines that contain alcohol whilst being treated with SUBLOCADE• Alcohol and some medicines may increase the sedative effects of SUBLOCADE

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

6. Are there any side effects?

Some common side effects include difficulty sleeping, anxiety, fatigue, weakness, numbness, flu-like symptoms, upset stomach, constipation and diarrhoea, abnormal liver function and injection site reactions. Cases of difficulty breathing and severe liver problems have been reported with SUBLOCADE.

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.

WARNINGS:

Risk of serious harm or death with intravenous administration

Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and blood clotting events, including life threatening blood clots in the lungs, if administered intravenously.

Hazardous and harmful use

Although SUBLOCADE is indicated for the treatment of opioid dependence, it still poses risks of hazardous and harmful use which can lead to overdose and death. The doctor will monitor your ongoing risk during treatment with SUBLOCADE.

Life threatening respiratory depression

Serious, life-threatening difficulty breathing may occur with the use of SUBLOCADE. Talk to your doctor about situations which may increase the risk of severe difficulty breathing.

Concomitant use of medicines affecting the central nervous system, including alcohol

Use of SUBLOCADE with anti-anxiety medicines, sedatives, antihistamines, some antidepressants, antipsychotics, cannabis and alcohol may result in profound sedation, severe difficulty breathing, coma and death.

SUBLOCADE

Active ingredient: Buprenorphine

Consumer Medicine Information (CMI)

This leaflet provides important information about using SUBLOCADE. 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 SUBLOCADE.

Where to find information in this leaflet:

1. [Why am I using SUBLOCADE?](#)
2. [What should I know before I use SUBLOCADE?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use SUBLOCADE?](#)
5. [What should I know while using SUBLOCADE?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using SUBLOCADE?

SUBLOCADE modified release injection contains the active ingredient buprenorphine. SUBLOCADE acts as a substitute for opioids like heroin, morphine, oxycodone or codeine and it helps withdrawal from opioids over a period of time.

SUBLOCADE is used as part of a medical, social and psychological treatment program for patients dependent on opioids.

SUBLOCADE must only be administered by your doctor or other healthcare professional.

2. What should I know before I use SUBLOCADE?

Warnings

Opioids can cause

- sleep apnoea (stopping breathing from time to time while sleeping) which can lead to low levels of oxygen in the blood. Tell your doctor if you have a history of sleep

apnoea or if anyone notices you stop breathing from time to time whilst sleeping.

- a decreased level of hormones in the blood caused by a problem with the adrenal glands. The effects of these hormone changes may include nausea, vomiting, loss of appetite, feeling very tired and weak, feeling dizzy, or low blood pressure.

- an increased level of the hormone 'prolactin' and decreased level of sex hormones in the blood.

Tell your doctor if you notice any of these symptoms. You may need blood tests, and your doctor may tell you to stop using SUBLOCADE.

Do not use SUBLOCADE if:

- you are allergic to buprenorphine or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- you have serious problems with your liver, or if your doctor detects the development of a serious liver problem during treatment.
- you are under the age of 18 years.
- you have serious breathing problems.
- you are intoxicated due to CNS depressant medicines (e.g. sedative/hypnotics, narcotic pain killers, anti-anxiety or antipsychotic medicines), alcohol or have delirium tremens (the 'shakes' and hallucinations).
- the package is torn or shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions such as asthma or other breathing problems, thyroid problems, prostate problems, problems with excess alcohol use, problems with drowsiness, Addison's disease, Kyphoscoliosis (hunchback disease), low blood pressure, urination problems, kidney problems, liver problems, if you have head injuries or have a condition where you have

increased pressure within your head, if you have problems related to the biliary tract, if you have a history of seizures or If you have severe mental problems or hallucinations (seeing or hearing things that are not really there).

- take any medicines for any other condition.

Some people have died from respiratory failure (inability to breathe) when using benzodiazepines (medicines used to treat anxiety or sleeping problems), or other depressants such as alcohol or other opioids at the same time as buprenorphine. For further information please discuss with your doctor.

Buprenorphine may cause fatal respiratory failure in children who accidentally ingest it.

SUBLOCADE can cause withdrawal symptoms (dependence). Withdrawal signs and symptoms were not observed in the month following discontinuation of SUBLOCADE. Considering the long-acting characteristic, any withdrawal signs and symptoms that may occur would be expected to be delayed.

If you stop receiving injections of SUBLOCADE, your doctor may want to monitor you for several months for signs and symptoms of withdrawal and treat appropriately due to the long-acting characteristic of this medicine.

Athletes should be aware that this medicine may cause a positive reaction to "anti-doping" tests.

The safety and effectiveness in patients over 65 years of age have not been established.

SUBLOCADE forms a depot following subcutaneous injection. Serious harm or death could result if injected intravenously. SUBLOCADE must NOT be injected intravenously, intramuscular or intradermally.

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.

Use of SUBLOCADE or other opioids by the mother during pregnancy may result in withdrawal symptoms in the baby following birth, this is called Neonatal Abstinence Syndrome. Neonatal Abstinence Syndrome is a condition that includes disturbances to a newborn baby's nervous, gastro-intestinal and breathing systems. Not all babies who are exposed to SUBLOCADE in this way will have withdrawal symptoms. Talk to your doctor if you become pregnant or plan to become pregnant during treatment with SUBLOCADE. Your doctor will help you consider the risks and benefits of continued treatment and plan for monitoring your baby following birth. Due to the long duration of buprenorphine effect, your baby will be monitored for several days at the end of pregnancy for effects on breathing and for withdrawal symptoms.

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 SUBLOCADE and affect how it works.

- medicines containing alcohol
- certain medicines for treating HIV/AIDS
- certain medicines for treating fungal and bacterial infections
- strong pain killers
- cough medicines containing opioid-related substances
- certain antidepressants including monoamine oxidase inhibitors
- certain medicines used to treat fits or epilepsy (anti-convulsants)
- sedating antihistamines
- sedatives
- alcohol
- anti-anxiety medicines
- certain medicines for high blood pressure
- antipsychotic medicines
- naltrexone

Tell your doctor if you are scheduled to have surgery using a general anaesthetic.

Some people have died when using sedatives (benzodiazepines) or other depressants, alcohol or other opioids at the same time as buprenorphine. You should not use benzodiazepines (medicines used to treat anxiety or sleep disorders) whilst you are taking SUBLOCADE unless they are prescribed by your doctor.

Alcohol and certain other medicines (as listed above) may increase the sedative effects of buprenorphine which can make driving and operating machinery hazardous.

Do not drink alcohol or take medicines that contain alcohol whilst you are being treated with SUBLOCADE.

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

4. How do I use SUBLOCADE?

How much to use

- SUBLOCADE must only be administered by your doctor or other healthcare professional.
- The recommended first two doses of SUBLOCADE are 300 mg. The subsequent dosing will be selected by your doctor based on clinical assessment of your condition.
- Because SUBLOCADE lasts a long time, maintenance doses should be given monthly and separated by a minimum of 26 days between doses.
- Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you.

How SUBLOCADE is used

- SUBLOCADE is injected under the skin in the abdomen, thigh, buttock or back of the upper arm by your doctor or other healthcare professional only.
- Your doctor will tell you when you need your next injection. It is important not to miss your scheduled dose.
- **SUBLOCADE must NOT be injected intravenously, intramuscularly or intradermally.**
- SUBLOCADE is only for adults.

If you forget to use SUBLOCADE

It is important to remember to attend your next appointment to receive your next SUBLOCADE injection.

If you cannot keep your appointment for your next SUBLOCADE injection, call your healthcare professional right away so another appointment can be made as soon as possible.

Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you.

Because SUBLOCADE lasts a long time, if you stop receiving injections of SUBLOCADE, you should be monitored for several months for symptoms of withdrawal so you can be treated appropriately.

If you use too much SUBLOCADE

Because SUBLOCADE will be administered to you under medical supervision, it is unlikely that you will be given too much.

If you think that you or anyone else may have received too much SUBLOCADE, 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.

Symptoms of an overdose with SUBLOCADE may include severe:

- drowsiness, dizziness or difficulty thinking
- drop in blood pressure
- difficulty breathing

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

When seeking medical attention, take this leaflet with you to show the doctor or healthcare professional.

5. What should I know while using SUBLOCADE?

Things you should do

If you are about to start on any new medicine, remind your doctor, nurse and pharmacist who treat you that you are using or will be starting SUBLOCADE.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using SUBLOCADE.

It may affect other medicines used during surgery.

Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- experience hypersensitivity reactions such as swelling of the face, lips, mouth or throat, or severe difficulty in breathing, or
- experience severe liver problems such as intense fatigue, no appetite, your skin and eyes look yellow, or you have light coloured bowel motions or dark coloured urine.
- experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.
- have difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time.

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

Things you should not do

- do not attempt to tamper with the medicine once given by your healthcare provider.
- do not rub or massage the injection site and be aware of the placement of any restrictive clothing such as belts, waistbands or sleeves.
- **do not give your medicine to anyone else, even if they have the same condition as you.**

Things to be careful of

- SUBLOCADE may cause your blood pressure to drop suddenly, causing you to feel dizzy if you get up too quickly from sitting or lying down.
- if you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
- if you stop using SUBLOCADE and if you start using opioids again, your sensitivity to opioids may change which could be dangerous. You should talk to your doctor before you start using opioids again.
- SUBLOCADE contains a narcotic that can be a target for people who abuse prescription medicines or street drugs.

Treating pain, emergencies and anaesthesia

While on SUBLOCADE situations may arise where you need to be treated for pain or may require anaesthesia. SUBLOCADE can interfere with the action of some pain treatments. In the event of an emergency, it is important you and your family or friends inform your healthcare provider or Emergency Room staff that you are being treated with SUBLOCADE. For 6 months after stopping SUBLOCADE, you should continue to inform your healthcare providers you have been treated with

SUBLOCADE because SUBLOCADE effect can last for a long time.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how SUBLOCADE affects you.

SUBLOCADE may cause drowsiness, which may be made worse if you also drink alcohol or take sedatives or anti-anxiety medicines. If you are drowsy, do not drive or operate machinery.

Drinking alcohol

Do not drink alcohol or take medicines that contain alcohol whilst you are being treated with SUBLOCADE.

Tell your doctor if you drink alcohol.

Looking after your medicine

The pharmacy, clinic or hospital where you receive your treatment will store SUBLOCADE under the required conditions.

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.

Less serious side effects

Less serious side effects	What to do
Pain-related effects: <ul style="list-style-type: none"> • pain in abdomen, back, arms, legs, joints and muscles, leg cramps, muscle weakness • headache, migraine • chest pain Gastrointestinal effects: <ul style="list-style-type: none"> • upset stomach and diarrhoea • nausea, vomiting, constipation, poor appetite • abnormal liver function General effects: <ul style="list-style-type: none"> • difficulty sleeping, anxiety • fatigue, weakness, numbness • sleepiness, dizziness, fainting, vertigo • flushing, feeling of warmth • rash and itching • tooth disorders • abnormal vision • low sex drive, impotence • urinary tract infection Injection site reactions:	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> • redness, pain, itching, nodule just under the skin Flu-like symptoms: <ul style="list-style-type: none"> • chills, fever, sore throat, coughing, runny nose and sweating Breathing related <ul style="list-style-type: none"> • difficulty breathing • cough, respiratory infection 	

Serious side effects

Serious side effects	What to do
Liver problems: <ul style="list-style-type: none"> • severe fatigue • you have no appetite • your skin and eyes look yellow • you have light coloured bowel motions or dark coloured urine Hypersensitivity reactions: <ul style="list-style-type: none"> • swelling of the face, lips, mouth or throat • severe difficulty breathing Severe injection site reactions: <ul style="list-style-type: none"> • signs of infection at the injection site such as pain, redness, swelling, itching and warmth. Signs of overdose: <ul style="list-style-type: none"> • severe drowsiness, dizziness or difficulty thinking • severe drop in blood pressure • severe difficulty breathing 	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.

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

For adverse event reporting please contact:

Indivior Pty Ltd

Tel: +800-270-81901

PatientSafetyRoW@indivior.com

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 SUBLOCADE contains

Active ingredient (main ingredient)	Buprenorphine
Other ingredients (inactive ingredients)	Polyglactin N-methyl-2-pyrrolidone
Potential allergens	None known

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

What SUBLOCADE looks like

SUBLOCADE 100 mg/0.5 mL modified release injection solution is supplied in a single use dose in a 1 mL plastic syringe with a plunger stopper, together with a 19 G 16mm pre-packaged safety needle (AUST R 303476).

SUBLOCADE 300 mg/1.5 mL modified release injection solution is supplied in a single use dose in a 2.25 mL plastic syringe with a plunger stopper, together with a 19 G 16mm pre-packaged safety needle (AUST R 303753).

Each assembled syringe with plastic plunger rod is supplied in an aluminium foil-laminate pouch containing an oxygen absorbing desiccant. The pouch is in a labelled paperboard carton along with a sterile safety needle and labelling.

SUBLOCADE 100mg/0.5mL and 300mg/1.5mL are supplied in a single use pack.

Who distributes SUBLOCADE

SUBLOCADE is distributed in Australia by:

Indivior Pty Ltd

78 Waterloo Road

Macquarie Park NSW 2113

Australia

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