SUBLOCADE®

Buprenorphine

Consumer Medicine Information

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 thrombo-embolic events, including life threatening pulmonary emboli, 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 respiratory depression may occur with the use of SUBLOCADE. Talk to your doctor about situations which may increase the risk of respiratory depression.
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, respiratory depression, coma and death.

What is in this leaflet?

This leaflet answers some common questions about SUBLOCADE. It does not contain all the available information. 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 taking SUBLOCADE against the benefits they expect it will have for you.

If you have any concerns about SUBLOCADE, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What is SUBLOCADE used for?

SUBLOCADE is used as part of a medical, social and psychological treatment program for patients dependent on opioids like heroin, morphine, oxycodone or codeine. SUBLOCADE is used to help patients overcome this medical condition. SUBLOCADE is used after patients started treatment with a buprenorphine-containing product.

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

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

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

Before you use SUBLOCADE

SUBLOCADE is not suitable for everyone.

When you must not use it

- If you have serious problems with your liver, or if your doctor detects the development of a serious liver problem during treatment.
- If you are under the age of 18 years.
- If you are allergic to buprenorphine or to any of the other ingredients in this medicine (see Product Description below).
- If you have serious breathing problems.
- If 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).

SUBLOCADE should not be used if the package is torn or shows signs of tampering.

Before you start to use it

Tell your doctor if you have any of the following before treatment, or develop them during treatment, as your doctor may need to adjust your dose of SUBLOCADE:

- 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
- if you have severe mental problems or hallucinations (seeing or hearing things that are not really there)
- if you are pregnant or become pregnant during treatment with SUBLOCADE
- If you are breast-feeding.

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.

Use in pregnancy may lead to neonatal abstinence syndrome. 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.

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 or intramuscularly.

Your doctor may ask you to have additional blood tests to see if this medication is right for you.

Taking Other Medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop, before you begin treatment with SUBLOCADE.

A number of medicines may alter the effects of SUBLOCADE. These include:

- 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.

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

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

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.

How to use SUBLOCADE

Do not use SUBLOCADE to treat any condition other than the one prescribed for by your doctor.

This medicine is given by your doctor or other healthcare professional. 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 or intramuscularly.

How much to use

SUBLOCADE is only for adults.

The recommended first two doses following an induction on a buprenorphine-containing product is 300 mg monthly. The subsequent dosing may be selected by your doctor based on clinical assessment of your condition. In consideration of the long duration of action, SUBLOCADE 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.

If you miss a dose of SUBLOCADE

If you cannot keep your appointment for your next administration of SUBLOCADE, make sure you call your health care 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.

If you stop receiving injections of SUBLOCADE, you should be monitored for several months for signs and symptoms of withdrawal and treated appropriately due to the long acting characteristic of this medicine.

If you take too much (overdose)

The medicine will be given to you under medical supervision; it is therefore unlikely that you will be given too much.

If you think that you or anyone else may have received too much SUBLOCADE, immediately telephone your doctor or National Poison Centre (in Australia telephone 13 11 26 or in New Zealand telephone 0800 POISON or 0800 764 766),

Keep telephone numbers for these places handy.

While you are using SUBLOCADE

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using SUBLOCADE.

Tell any other doctors, dentists, nurses and pharmacists who treat you that you are using SUBLOCADE.

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

It may affect other medicines used during surgery.

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

Things you must 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 belts or clothing waistbands.

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 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.

Be careful driving or operating machinery until you know how SUBLOCADE affects you.

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.

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

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. It is important you inform your health care provider that you are treated with 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. After stopping SUBLOCADE you should continue to inform your health care providers you have been treated with SUBLOCADE for 6 months after your last dose as SUBLOCADE effect can last for a long time.

Side effects

Like all medicines, SUBLOCADE may have unwanted side effects which may need medical treatment.

Ask your doctor or pharmacist to answer any questions you may have.

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

Some of the most common side effects reported with the use of buprenorphine were:

- difficulty sleeping, anxiety
- fatigue, weakness, numbness
- pain in the abdomen, back, arms, legs, joints and muscles, leg cramps, muscle weakness
- flu-like symptoms such as chills, fever, sore throat,

coughing, runny nose and sweating
- upset stomach and diarrhoea
- reactions at the injection site (redness, pain, itching, nodule just under the skin)
- Abnormal liver function

Other side effects which have occurred are:

- tooth disorders
- headache, migraine
- sleepiness, dizziness, fainting, vertigo
- abnormal vision
- difficulty sleeping
- chest pain
- pain in joints, muscles, back, stomach, cramps
- flushing, feeling of warmth
- difficulty breathing
- cough, respiratory infection
- nausea, vomiting, constipation, diarrhoea, poor appetite
- rash and itching
- low sex drive, impotence
- urinary tract infection

If you think you are suffering from any of the above side-effects, or any other side effects, you should tell your doctor immediately.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital. You may need urgent medical attention.

- There have been rare cases of life-threatening severe hypersensitivity reactions with symptoms of severe difficulty in breathing, swelling of the face, lips, mouth or throat.
- Some cases of severe liver problems have occurred during treatment. If you develop severe fatigue, have no appetite or if your skin or eyes look yellow, you have light coloured bowel motions or dark coloured urine, tell your doctor immediately.

Other side-effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

After Using SUBLOCADE

If you stop receiving SUBLOCADE and start using opioids again, you are at risk of being more sensitive to opioids, which could be dangerous. You should talk to your doctor if you start using opioids again.

Storage

Store at 2°C - 8°C. Refrigerate. Do not freeze.

Once outside the refrigerator this product may be stored in its original packaging at room temperature (below 25°C) for up to 12 weeks prior to injecting.

SUBLOCADE should be discarded if not refrigerated for longer than 12 consecutive weeks.

Do not use after the expiry date which is stated on the carton and pouch labels.

Once the medicine is administered, the needle guard should be locked into place by pushing it against a hard surface such as a table.

All syringe components should be disposed of in a secure sharps disposal container.

As with all medicines, keep out of the reach and sight of children.

Product Description

What it 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.

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.

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

Ingredients

Each SUBLOCADE prefilled syringe contains either 0.5 mL modified release injection solution (corresponding to 100 mg buprenorphine) or 1.5 mL modified release injection solution (corresponding to 300 mg buprenorphine) in Indivior's proprietary buprenorphine gel depot delivery system.

Inactive ingredients:

Polyglactin

N-methyl-2-pyrrolidone.

Supplier

Supplied in New Zealand by:

Pharmacy Retailing (NZ) Ltd
t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Mangere
Auckland 2022
Telephone (09) 918 5100
Fax: (09) 918 5101

For adverse event reporting please contact:
https://nzphvc.otago.ac.nz/reporting/

Indivior Pty Ltd
+800-270-81901
PatientSafetyRoW@indivior.com

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