Sublocade®
(buprenorphine extended-release injection)

Guide to SUBLOCADE® Administration

SUBLOCADE® is indicated for the management of moderate to severe opioid use disorder in adult patients who have been inducted and clinically stabilized on a transmucosal buprenorphine-containing product.

SUBLOCADE® should be used as part of a complete treatment plan that includes counselling and psychosocial support.

SUBLOCADE® must only be administered subcutaneously in the abdominal region by a healthcare provider.

INDIVIOR®

SUBLOCADE®

Patient selection

- Patients appropriate for SUBLOCADE® are adults who have agreed to be treated for Opioid Use Disorder (OUD) and who have undergone induction on a buprenorphine-containing product to suppress opioid withdrawal signs and symptoms.
- Periodic assessment is necessary to determine effectiveness of the treatment plan and overall patient progress. When evaluating the patient, examine the injection site for signs of infection or evidence of tampering or attempts to remove the depot.
- Due to the chronic nature of OUD, the need for continuing a medication-assisted treatment plan should be re-evaluated periodically. If considering stopping the treatment plan, the clinical status of the patient should be considered.
- If SUBLOCADE® is discontinued, the patient should be monitored for several months for signs and symptoms of withdrawal and treated appropriately. After steady-state has been achieved (4-6 months), patients discontinuing SUBLOCADE® may have detectable plasma levels of buprenorphine for 12 months or longer. The correlation between plasma concentrations of buprenorphine and those detectable in urine is not known.

Storage, stability and disposal

- SUBLOCADE® is available as a sterile, clear, viscous, colourless to yellow to amber solution in a single dose, prefilled syringe with safety needle.

- Store at 2-8°C (35.6-46.4°F).

- Once outside the refrigerator, this product may be stored in its original packaging at room temperature, 15-30°C (59-86°F), for up to 7 days prior to administration.

- Discard SUBLOCADE® if left at room temperature for longer than 7 days.

Special handling instructions

- Handle SUBLOCADE® with adequate security and accountability.
- After administration, syringes should be properly disposed of per facility procedure.

SUBLOCADE® SHOULD ONLY BE ADMINISTERED BY A HEALTHCARE PROVIDER. SUBLOCADE® IS AVAILABLE ONLY THROUGH A CONTROLLED DISTRIBUTION PROCESS.

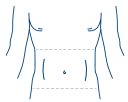
Recommended dose and dosage adjustment

- Patients should first undergo induction and stabilization by initiating a transmucosal buprenorphine-containing product, delivering the equivalent of 8-24 mg/day of buprenorphine for a minimum of 7 days.
- Initiation with transmucosal buprenorphine-containing products should be based on instructions in the specific product label.
- Following induction and stabilization, patients can be transitioned to SUBLOCADE®, starting with 300 mg/month for two months, followed by a maintenance dose of 100 mg/month.
- The maintenance dose may be increased to 300 mg/month only if the patient does not demonstrate satisfactory clinical response to and can tolerate the 100 mg dose.
  - In clinical trials, the 300 mg/month maintenance dose did not provide additional efficacy as compared to the 100 mg/month dose and was associated with a higher incidence of adverse events and study discontinuations.
- SUBLOCADE® has a long half-life and should only be administered monthly.
- A minimum of 26 days is required between consecutive doses.

The clinical efficacy of starting the SUBLOCADE® part of the treatment at 100 mg has not been studied.

Administration

Important information



- For abdominal subcutaneous injection only.

- To be administered by a healthcare provider only.

- Please read the instructions carefully before handling the product.

- As a universal precaution, always wear gloves.

- Remove SUBLOCADE® from the refrigerator prior to administration. The product requires at least 15 minutes to reach room temperature. Do not open the foil pouch until the patient has arrived for his or her injection.

- Discard SUBLOCADE® if left at room temperature for longer than 7 days.

- Do not attach the needle until the time of administration.

Administration

Important information about the TERUMO SurGuard3® Safety Hypodermic Needle

- Non-toxic
- Non-pyrogenic
- This device has no components made of natural rubber latex.

The TERUMO SurGuard3® Safety Hypodermic Needle is packaged with SUBLOCADE®. No other needle should be used with SUBLOCADE®.

- After withdrawal of the needle from the body, the attached needle safety sheath can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

WARNINGS

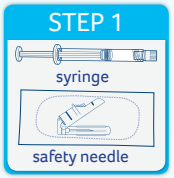
- Handle with care to avoid needle sticks.
- Use once and discard immediately in accordance with local safety standards.

CAUTIONS

- If needle is bent or damaged, do not attempt to straighten needle. Do not use the product.
- Do not attempt to deactivate the safety device by forcing the needle out of the safety sheath.
- For single use only. Do not reuse. Do not resterilize.

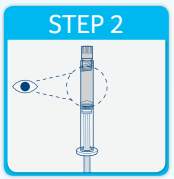
PRECAUTIONS

- Keep hands behind needle at all times during use and disposal.
- Observe universal precautions on all patients.
- Do not use if the unit package or product has been damaged or contaminated.
- Do not store at extreme temperature and humidity. Avoid direct sunlight.



GETTING READY

- Remove the foil pouch and safety needle from the carton. Open the pouch and remove the syringe.
- Discard the oxygen absorber pack. It is not needed.

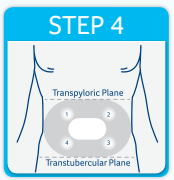


CHECK THE LIQUID CLARITY

- Inspect the medication visually to make sure it does not contain contaminants or particles.
- SUBLOCADE® ranges from colourless to yellow to amber. Variations of colour within this range do not affect the potency of the product.

ATTACH THE SAFETY NEEDLE

- Remove the cap from the syringe and the safety needle supplied in the carton from its sterile package.
- Gently twist the needle clockwise until it is tight and firmly attached.
- Do not remove the plastic cover from the needle.

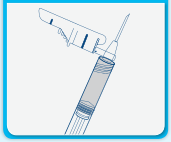


PREPARE THE ABDOMINAL INJECTION SITE

- Choose an injection site on the abdomen between the transpyloric and transtubercular planes with adequate subcutaneous tissue that is free of skin conditions (e.g., nodules, lesions, excessive pigment). It is recommended that the patient is in the supine position.
- Do not inject into an area where the skin is irritated, reddened, bruised, infected or scarred in any way.
- Clean the injection site well with an alcohol swab.
- To avoid irritation, rotate injection sites following a pattern similar to the illustration.
- Record the location of the injection to ensure that a different site is used at the time of the next injection.

Administration

STEP 5



REMOVE EXCESS AIR FROM SYRINGE

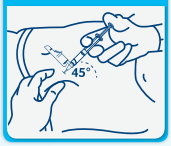
- Hold the syringe upright for several seconds to allow air bubbles to rise. Due to the viscous nature of the medication, bubbles will not rise as quickly as those in an aqueous solution.
- Remove needle cover and slowly depress the plunger to push out the excess air from the syringe.
- Small bubbles may remain in the medication. Large air gaps, however, can be minimized by pulling back on the plunger rod to pop air bubbles prior to expelling the air very slowly. Air should be expelled very carefully to avoid loss of medication.
- If medication is seen at the needle tip, pull back slightly on the plunger to prevent medication spillage.

STEP 6

PINCH THE INJECTION SITE

- Pinch the skin around the injection area. Be sure to pinch enough skin to accommodate the size of the needle. Lift the adipose tissue from the underlying muscle to prevent accidental intramuscular injection.

STEP 7



INJECT THE MEDICATION

- SUBLOCADE® is for subcutaneous injection only. Do not inject intravenously OR intramuscularly.
- Insert needle fully into the abdominal subcutaneous tissue. Actual angle of injection will depend on the amount of subcutaneous tissue.
- Use a slow, steady push to inject the medication. Continue pushing until all the medication is given. The entire contents of the sterile prefilled syringe should be administered.

STEP 8

WITHDRAW THE NEEDLE

- Withdraw the needle at the same angle used for insertion and release the pinched skin. A small amount (approximately 0.1 mL) of SUBLOCADE® will remain in the needle and syringe and should be disposed of in an appropriate manner.
- Do not rub the injection area after the injection. If there is bleeding, apply a gauze pad or bandage but use minimal pressure.

STEP 9

LOCK THE NEEDLE GUARD AND DISCARD THE SYRINGE

- Lock the needle guard into place by pushing it against a hard surface such as a table.
- Dispose of all syringe components in a secure sharps disposal container.

STEP 10

INSTRUCT THE PATIENT

- Advise the patient that they may have a lump for several weeks that will decrease in size over time.
- Instruct the patient not to rub or massage the injection site and to be aware of the placement of any belts or clothing waistbands that could cause irritation of the injection site.

Important safety information

Clinical use:

SUBLOCADE® should be used as part of a complete treatment plan that includes counselling and psychosocial support. SUBLOCADE® must only be administered subcutaneously in the abdominal region by a healthcare provider.

There were no patients ≥65 years of age in the controlled clinical trial of SUBLOCADE®. In general, drug use for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, respiratory, and/or cardiac function, concomitant disease or other drug therapies. If the decision is made to prescribe SUBLOCADE® to individuals ≥65 years of age, patients should be monitored for signs and symptoms of toxicity or overdose.

Contraindications:

SUBLOCADE® is contraindicated in patients:

- with severe respiratory insufficiency: e.g., acute or severe bronchial asthma, chronic obstructive airway, status asthmaticus, acute respiratory depression, and/or cor pulmonale.
- with severe hepatic impairment.
- with acute alcoholism or delirium tremens.
- with known or suspected mechanical gastrointestinal obstruction (e.g., bowel obstruction or strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type).
- with suspected surgical abdomen (e.g., acute appendicitis or pancreatitis).
- with severe central nervous system (CNS) depression, increased cerebrospinal or intracranial pressure, and head injury.
- taking monoamine oxidase (MAO) inhibitors (or within 14 days of such therapy).
- with convulsive or seizure disorders.
- with congenital Long QT Syndrome or QT prolongation at baseline.
- with uncorrected hypokalemia, hypomagnesemia, or hypocalcemia.

Most serious warnings and precautions:

Incorrect Administration: Do not administer intravenously OR intramuscularly. SUBLOCADE® forms a solid mass following subcutaneous administration. Serious harm or death could result if administered intravenously.

Limitations of Use: SUBLOCADE® should only be administered by a healthcare provider.

Addiction, Abuse, and Misuse: Abuse and diversion of buprenorphine component of SUBLOCADE® is possible. All patients should be monitored regularly for the development of these behaviours or conditions.

Use During Pregnancy: SUBLOCADE® should not be used in women of childbearing potential who are not using an effective and reliable method of contraception. SUBLOCADE® should not be administered to pregnant women unless in the judgment of the physician, the potential benefit to the mother outweighs the risk to the fetus.

Life-Threatening Respiratory Depression: OVERDOSE: Serious, life-threatening, or fatal respiratory depression may occur with use of SUBLOCADE®. Infants exposed in-utero or through breast milk are at risk of life-threatening respiratory depression upon delivery or when nursed. Patients should be monitored for respiratory depression, especially immediately after SUBLOCADE® injection and following a dose increase. Misuse or abuse of SUBLOCADE® may pose a significant risk of overdose and death. Further instruct patients of the hazards related to taking opioids including fatal overdose.

Accidental Exposure: Accidental exposure to even one dose of SUBLOCADE® by individuals not physically dependent on opioids, especially children, can result in a fatal overdose of buprenorphine.

Interaction with Alcohol: The co-ingestion of alcohol with SUBLOCADE® should be avoided as it may result in dangerous additive effects, causing serious injury or death.

Neonatal Opioid Withdrawal Syndrome: Prolonged maternal use of SUBLOCADE® during pregnancy can result in a neonatal opioid withdrawal syndrome, which may be life-threatening. Prolonged maternal use of opioids during pregnancy can also result in neonatal respiratory depression.

Interaction with Other CNS Depressants: Risks from concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of SUBLOCADE® and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- Consider dose reduction of CNS depressants in situations of concomitant prescribing.
- Follow patients for signs and symptoms of respiratory depression and sedation.

Cardiac: SUBLOCADE® should not be used in patients with a history of Long QT Syndrome or an immediate family member with this condition or those taking Class IA/IC or III antiarrhythmic medications. Particular care should be exercised when administering SUBLOCADE® to patients who are suspected to be at an increased risk of experiencing torsade de pointes during treatment with a QTc-prolonging drug.

Other relevant warnings and precautions:

- Adrenal insufficiency.
- Orthostatic hypotension.
- Use in patients with circulatory shock.
- Dependence and risk of opioid withdrawal following discontinuation of SUBLOCADE®.
- Impaired mental and/or physical abilities needed for driving or operating hazardous machinery.
- Elevation of cerebrospinal fluid pressure.
- Effects in acute abdominal conditions.
- Elevation of intracholedochal pressure.
- Hepatitis and other hepatic events.
- Use in patients with impaired hepatic function.
- Allergic reactions/hypersensitivity.
- Peri-operative considerations for pain management.
- Serotonin syndrome
- Decreased sex hormones and related symptoms, including infertility.
- Use in debilitated patient and patients with hypothyroidism; CNS depression or coma; toxic psychoses; prostatic hypertrophy or urethral stricture; acute alcoholism; delirium tremens; or kyphoscoliosis.
- Use in opioid-naïve patients.
- Use in pregnant or breastfeeding women and during labour and delivery.

For more information:

Please consult the product monograph at https://health-products.canada.ca/dpd-bdpp/index-eng.jsp for important information relating to adverse reactions, drug interactions, and dosing which have not been discussed in this piece.
The product monograph is also available by: emailing infoMIU@indivior.com or calling 1-877-782-6966.

Reference:

1. SUBLOCADE® Product Monograph. Indivior UK Limited. January 20, 2020.

INDIVIOR®

REVIEWED BY PAAB

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