****Insert information for**

ORDER AND/OR DELEGATED PROCEDURE:

The above Health Care Providers delegate the authority to the Registered Nurses and Registered Nurse Practitioners employed by Timmins & District Hospital to administer SUBLOCADE to registered patients of the Timmins & District Hospital Outpatient Sublocade® Clinic who have been prescribed SUBLOCADE by their primary care provider.

RECIPIENT CLIENTS:

Adult clients of the Timmins & District Hospital Out Patient Sublocade® Clinic who have agreed to be treated for Opioid Use Disorder and have been prescribed SUBLOCADE by their primary care provider after an induction of a transmucosal buprenorphine-containing product.

AUTHORIZED IMPLEMENTERS:

Physicians, Registered Nurse Practitioners and Registered Nurses* who have completed the SUBLOCADE Certification Program.

Registration Site for certification program.

*Registered Nurses who have administered two SUBLOCADE injections while supervised by a provider who is certified in SUBLOCADE injections.

INDICATIONS:

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 for a minimum of seven days.

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.

CONTRAINDICATIONS:

- Patients who are hypersensitive to this drug or any ingredient in the formulation, including any non-medicinal ingredient, or any component of the ATRIGEL® Delivery System.

- Patients with severe respiratory insufficiency: e.g. acute or severe bronchial asthma, chronic obstructive airway, status asthmaticus, acute respiratory depression and/or cor pulmonale.
- Patients with severe hepatic impairment.
- Patients with acute alcoholism or delirium tremens.
- Patients with known or suspected mechanical gastrointestinal obstruction (e.g. bowel obstruction or strictures) or any disease /conditions that affect bowel transit (e.g. ileus of any type).
- Patients with suspected surgical abdomen (e.g. acute appendicitis or pancreatitis). Patients with severe central nervous system (CNS) depression, increased cerebrospinal or intracranial pressure, and head injury.
- Patients taking monoamine oxidase (MAO) inhibitors (or within 14 days of such therapy).
- Patients with convulsive or seizure disorders.
- Congenital Long QT Syndrome or QT prolongation at baseline
- Uncorrected hypokalemia, hypomagnesemia, or hypocalcemia.
- Not indicated in pediatrics.

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.

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.
- 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.
- Not recommended to be used in nursing women and during labour and delivery unless, in the judgement of the primary care provider, the potential benefits outweigh the risks.

Life-threatening Respiratory Depression: OVERDOSE

- Serious, life-threatening or fatal respiratory depression may occur with use of SUBLOCADE.
- 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. Patients should be instructed on 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.
- SUBLOCADE must be kept in a locked fridge.

Interaction with Alcohol

- Avoid co-ingestion of alcohol with SUBLOCADE 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 Central Nervous System Depressants

- Risks from concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, and result in profound sedation, respiratory depression, coma, and death.
- Concomitant prescribing of SUBLOCADE and benzodiazepines or other CNS depressants should be reserved for patients in whom alternative treatment options are inadequate.
- A dose reduction of CNS depressants should be considered in situations of concomitant prescribing.
- Assess and follow patients for signs and symptoms of respiratory depression or sedation.

Cardiac

- QTc prolongation

- Orthostatic hypotension

Other Relevant Warnings and Precautions for SUBLOCADE

- Adrenal insufficiency
- Dependence and risk of opioid withdrawal with discontinuation of SUBLOCADE
- Caution patients about driving or operating hazardous machinery
- Elevation of cerebrospinal fluid pressure. Caution in patients with head injury, intracranial lesions, and other circumstances when cerebrospinal fluid pressure may be increased.
- Administer cautiously to patients with dysfunction of the biliary tract as elevates intracholedochal pressure.
- Hepatitis and other hepatic events. Caution in patients with moderate hepatic impairment.
- Pain management: Patients receiving SUBLOCADE should be treated with non-opioid analgesic whenever possible.
- Use with caution with other serotonergic drugs.
- SUBLOCADE should not be administered to opioid-naïve patients.
- Administer cautiously to patients > 65 years of age or older. Monitor for signs and symptoms of toxicity or overdose.

DOSAGE:

- The Registered Nurse/Registered Nurse Practitioner will administer SUBLOCADE as prescribed by the primary care provider.
- Patients must first have undergone an induction and stabilization with a transmucosal buprenorphine-containing product, delivering the equivalent of 8-24 mg/day of buprenorphine for a minimum of 7 days or earlier as per physician's discretion.
- 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.
- Maintenance dose can be increased to 300 mg/month only if the patient does not demonstrate satisfactory clinical response to and can tolerate the 100 mg dose.
- SUBLOCADE has a long half-life and should only be administered monthly. **A minimum of 26 days is required between consecutive doses.**

Missed Dose

- A patient who misses a dose should receive the next dose as soon as possible, with the following dose given no less than 26 days later.

ADMINISTRATION:

IMPORTANT

- For abdominal subcutaneous injection only.
- To be administered by health care professional only.
- The Registered nurse must 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.

Important information about the TERUMO SurGuard3® Safety Hypodermic Needle

The TERUMO SurGuard3® Safety Hypodermic Needle is non-toxic, non-pyrogenic, and has no component made of rubber latex.

- It 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 stick injury
- Use once and discard immediately in sharps container

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.

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.

Steps to administer:

Step 1 Getting Ready

- The Registered nurse will verify the physician/nurse practitioner's order.
- Perform hand hygiene. Put gloves on.
- Remove the foil pouch and safety needle from the carton.
- Open the pouch and remove the syringe.
- Discard the oxygen absorber pack, as it is not needed.

Step 2 Check the liquid clarity

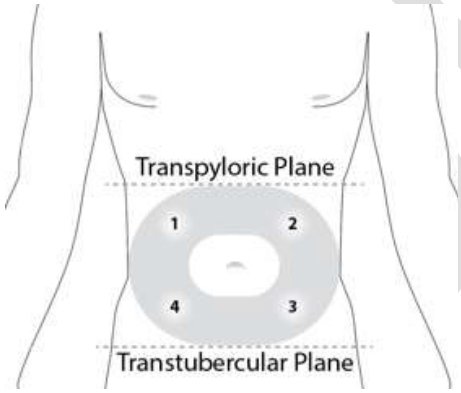
- Inspect the medication visually to make sure it does not contain contaminants or particles.
- Can range from colourless to yellow to amber. Variations of colour within this range do not affect the potency of the product.

Step 3 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.

Step 4 Prepare the abdominal injection site

- The patient should be in a supine position. Choose an injection site on the abdomen between the transpyloric and transtubercular planes with adequate subcutaneous tissue that is free of skin conditons (e.e nodules, lesions, excessive pigment).



- Do not inject into an area where the skin is irritated, reddened, bruised, infected or scarred in any way.
- Clean the injection site with an alcohol swab.
- To avoid irritation, rotate sites. Record the location of the injection to ensure that a different site is used at the time of the next injection.

Step 5 Remove excess air from syringe

- Hold syringe upright for several seconds to allow air bubbles to rise. The medication is viscous therefore they will not rise quickly.
- Remove the needle cover and slowly depress the plunger to push out the excess air from the syringe.
    - Small bubbles may remain in the medication. If there are large air gaps, pull back on the plunger rod to pop air bubbles prior to expelling the air slowly. Expel air 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. 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 mediation. Continue pushing until all medication is given.

Step 8 Withdraw needle

- Withdraw the needle at the same angle used for insertion and release the pinched skin.
- Do not rub the injection area after the injection. If there is bleeding, apply a gauze pad or bandage using 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 biohazard sharps container.

Steep 10 Instruct the patient

- Advise the patient that they may have a clump 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 that could cause irritation of the injection site.

CONSENT:

- The Registered Nurse will describe the procedure and indications to the patient.
- Consent for the procedure can be collected verbally.

DOCUMENTATION AND COMMUNICATION:

Administered SUBLOCADE to an individual should be recorded as part of the encounter detail form in online documentation system, as well as sending a record of administration to relevant service providers.

Recording should include the following:

- Date given (yyyy-mm-dd);
- Time given;
- Trade name of the product;
- Dose;
- Site;
- Route of administration;
- Expiry date; and
- Name and title of person administering the medication.

REVIEW AND QUALITY MONITORING GUIDELINES:

If an authorized staff member identified any issue related to using this directive, they should consult the manager or supervisor.

ADMINISTRATIVE APPROVALS:

APPROVING PRIMARY CARE PROVIDERS:

REFERENCES:

Indivior UK Limited:, SUBLOCADE Product Monograph, November 20, 2018
Retrieved February 26, 2021 https://pdf.hres.ca/dpd_pm/00048406.PDF