SUBLOCADE® CERTIFICATION IS REQUIRED BEFORE IT CAN BE PRESCRIBED FOR YOUR PATIENTS

SUBLOCADE (BUPRENORPHINE EXTENDED-RELEASE INJECTION) IS AVAILABLE ONLY THROUGH A CONTROLLED DISTRIBUTION PROCESS.[1]

To prescribe and order SUBLOCADE you must first receive certification.
Visit the SUBLOCADE Certification Program: www.sublocadecertification.ca.

YOU WILL BE GUIDED THROUGH THE FOLLOWING STEPS:

1. Register for the SUBLOCADE Certification Program.
2. Review the program to:
   - Learn how to prescribe and administer SUBLOCADE
   - Become familiar with warnings, precautions and safety information related to SUBLOCADE
3. At the end of the program you will be prompted to take a certification quiz.
4. Upon successful completion of the quiz, print or save a copy of your certification.

If you are a prescribing healthcare professional, you MUST provide a copy of the certification to the appropriate pharmacist in order to obtain SUBLOCADE. You should not prescribe SUBLOCADE without this certification. Your pharmacist will not dispense SUBLOCADE without first obtaining a copy of your certification.

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™

N Sublocade®
(buprenorphine extended-release injection)

Important Safety Information

Clinical use:
No data are available in pediatrics (<18 years of age). SUBLOCADE® is not indicated in pediatrics.

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.

Contraindications:
SUBLOCADE is contraindicated in 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.
- 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 Central Nervous System Depressants: Risks from concomitant use of opioids with benzodiazepines or other central nervous system (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: QTc prolongation.

Other relevant warnings and precautions:

- Risk of Serious Harm or Death with Intravenous Administration. **Do not administer intravenously OR intramuscularly.**
- Risk of tissue damage from intramuscular injection.
- Adrenal insufficiency.
- Cardiovascular: Orthostatic hypotension in ambulatory patients.
- QTc prolongation: 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 antiarrhythmic medications, Class IC antiarrhythmic medications, or Class 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. The use of SUBLOCADE in patients with circulatory shock should be avoided.
- Dependence and risk of opioid withdrawal with discontinuation of SUBLOCADE.
- Patients should be cautioned about driving or operating hazardous machinery.
- Elevation of cerebrospinal fluid pressure: Caution in patients with head injury, intracranial lesions, and other circumstances when cerebrospinal pressure may be increased.
- Effects in acute abdominal conditions.
- Elevation of intracholedochal pressure: Administer with caution to patients with dysfunction of the biliary tract.
- Hepatitis and other hepatic events.
- Use in patients with impaired hepatic function: Caution in patients with pre-existing moderate hepatic impairment. SUBLOCADE should not be given to patients with pre-existing severe hepatic impairment. Patients who develop severe hepatic impairment while receiving SUBLOCADE should be discontinued and additional doses should not be administered.
- Monitoring and laboratory tests to assess liver function.
- Pain management: Treat patients receiving SUBLOCADE with a non-opioid analgesic whenever possible. If required, treat patients with high affinity full opioid analgesic under physician supervision.
- Serotonin syndrome: Use with caution in combination with other serotonergic drugs.
- Reproduction/function/fertility.
- SUBLOCADE should not be administered to opioid-naïve patients.
- Pregnancy: Reproductive and developmental toxicity studies in animals have demonstrated a range of adverse effects on embryo-fetal, fetal, pre- and postnatal development with SUBLOCADE, buprenorphine, and most notably with the excipient *N*-methyl-2-pyrrolidone (NMP). SUBLOCADE use should be avoided in women of childbearing potential who are not using an effective and reliable method of contraception or are judged not able to comply with contraceptive methods. Pregnant women using SUBLOCADE should not discontinue their medication abruptly as this can cause pregnancy complication such as miscarriage or still-birth. If SUBLOCADE is discontinued, it should be under medical supervision to avoid serious adverse events to the fetus, withdrawal symptoms in the pregnant woman and potential relapse to illicit drug use. The decision to discontinue SUBLOCADE therapy during pregnancy should be made by the prescriber, patient, and counsellor/support staff as part of a comprehensive treatment plan. The risk of relapse following withdrawal of treatment should be considered.
- Nursing women, labour and delivery: SUBLOCADE is not recommended to be used in nursing women and during labour and delivery unless, in the judgement of the physician, the potential benefits outweigh the risks.

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

Report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

You can also report any suspected side effects associated with the use of SUBLOCADE by email: PatientSafetyNA@indivior.com, or by calling the Indivior Medical Information Unit: 1-877-782-6966.

Reference: 1. SUBLOCADE Product Monograph. Indivior UK Limited, November 5, 2019.

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