WESTBROOK
Health Services
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Sublocade Patient Education

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with transmucosal buprenorphine-containing product (suboxone), followed by dose adjustment for a minimum of 7 days.
SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.
SUBLOCADE is once monthly buprenorphine treatment designed to deliver sustained therapeutic plasma level to help disrupt the drivers of OUD.
CONTRAINDICATIONS: SUBLOCADE should not be administered to patients who are hypersensitive to buprenorphine or any component of the ATRIGEL delivery system.
WARNINGS AND PRECAUTIONS:

- Patients will be monitored for conditions indicative of diversion or progression of opioid dependence and addictive behaviors.
- Risk of life-threatening respiratory depression and concomitant use of benzodiazepines or other CNS depressants with buprenorphine.
- Use with caution in patients with compromised respiratory function (e.g., COPD, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression).
- Opioids can cause sleep related breathing disorders: e.g., central sleep apnea.) • Neonatal Opioid Withdrawal Syndrome: (NOW); may be life threatening if not recognized in neonates.
- Adrenal Insufficiency.
- Discontinuation of SUBLOCADE treatment; Due to the long-acting nature of SUBLOCADE, if treatment is discontinued, monitor patients for several months for withdrawal and treat appropriately. Pts may have detectable levels of buprenorphine for a prolonged period of time after treatment. Consideration of drug-drug interactions, buprenorphine effects, and analgesia may continue to be relevant for several months after the last injection.
- Risk of Hepatitis, Hepatic Events.
- Hypersensitivity Reactions: most commonly rashes, hives, pruritus, some cases of angioneurotic edema and anaphylactic shock have also been reported.
- Precipitation of Opioid Withdrawal In Patients Dependent on Full Agonist Opioids: Buprenorphine may precipitate opioid withdrawal signs and symptoms in persons who are currently physically dependent on full opioid agonists such as heroin, morphine, or

methadone before the effects of the full opioid agonist have subsided. Clinicians will verify that patients have tolerated and are dose adjusted on transmucosal buprenorphine before subcutaneously injecting SUBLOCADE.

- Treatment of Emergent Acute Pain: If opioid therapy is required, patients may be treated with a high-affinity full opioid analgesic under supervision of physician. Hlgher doses, therefore, higher potential for toxicity. Patients should instruct family members in the event of emergency to inform treating healthcare provider that patient is physically dependent on an opioid and that patient is being treated with SUBLOCADE.
- Use in Opioid Naïve Patients: Because death has been reported for opioid naïve individuals who receive buprenorphine sublingual tablet, SUBLOCADE is not appropriate for use in opioid naïve patients.
- Impairment of Ability to Drive or Operate Machinery.
- Orthostatic Hypotension: Buprenorphine may produce orthostatic hypotension.
- Elevation of Cerebrospinal Fluid Pressure: Use with caution in patients with head injury.
- Elevation of Intracholedochal Pressure: Use with caution in patients with dysfunction of the biliary tract.
- Effects in Acute Abdominal Conditions: Buprenorphine may obscure the diagnosis or clinical course of patients with acute abdominal conditions.
- Unintentional Pediatric Exposure: Buprenorphine can cause severe, possibly fatal, respiratory depression in children who are accidentally exposed to it.
- SUBLOCADE may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.
- ADVERSE REACTIONS: Adverse reactions commonly associated with SUBLOCADE during clinical trials were constipation, headache, nausea, vomiting, increased hepatic enzymes, fatigue, and injection site pain and pruritus. This is not a complete list of potential adverse events. Please see the full Prescribing information for a complete list.
- Please report any injection site issues such as bruising, redness, or pruritus to nursing staff at (304) 485-1721 X 163 in Wood County, (304) 927-5200 in Roane County, (304) 6842656 in Pleasants County, (304) 643-2996 in Ritchie County, and (304) 372-6833 in Jackson County.

  By signing below you attest you understand SUBCLOCADE uses and cautions/warning/SE and have been given printed SUBLOCADE safety information.

Client Signature:_____Date:_____

Nurse Signature: _____Date:_____

MEDICATION GUIDE

SUBLOCADE (SUB-lo-kade) (buprenorphine extended-release) injection, for subcutaneous use, (CIII)

What is the most important information I should know about SUBLOCADE?

- Because of the serious risk of potential harm or death from self-injecting SUBLOCADE into a vein (intravenously), it is only available through a restricted program called the SUBLOCADE REMS Program.
- SUBLOCADE is not available in retail pharmacies.
- Your SUBLOCADE injection will only be given to you by a certified healthcare provider.

SUBLOCADE contains a medicine called buprenorphine. Buprenorphine is an opioid that can cause serious and life-threatening breathing problems, especially if you take or use certain other medicines or drugs.

Talk to your healthcare provider about naloxone. Naloxone is a medicine that is available to patients for the emergency treatment of an opioid overdose. If naloxone is given, you must call 911 or get emergency medical help right away to treat an overdose or accidental use of an opioid.

SUBLOCADE may cause serious and life-threatening breathing problems. Get emergency help right away if you:

- feel faint
- feel dizzy
- are confused
- Feel sleepy or uncoordinated
- are breathing slower than normal

Do not take certain medicines during treatment with SUBLOCADE. Taking other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) while on SUBLOCADE can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

- In an emergency, have family members tell emergency department staff that you are physically dependent on an opioid and are being treated with SUBLOCADE.
- You may have detectable levels of SUBLOCADE in your body for a long period after stopping treatment with SUBLOCADE.

What is SUBLOCADE?

SUBLOCADE is a prescription medicine used to treat adults with moderate to severe addiction (dependence) to opioid drugs (prescription or illegal) who:

- have received treatment with an oral transmucosal (used under the tongue or inside the cheek) buprenorphinecontaining medicine for 7 days **and**
- are taking a dose that controls withdrawal symptoms for at least seven days.
- SUBLOCADE is part of a complete treatment plan that should include counseling.

Who should not take SUBLOCADE?

Do not use SUBLOCADE if you are allergic to buprenorphine or any ingredient in the prefilled syringe (ATRIGEL@ delivery system). See the end of this Medication Guide for a list of ingredients in SUBLOCADE.

Before starting SUBLOCADE, tell your healthcare provider about all your medical conditions, including if you have:

trouble breathing or lung an enlarged prostate (men) • a head injury or brain problems problems urinating problem

- a curve in your spine that liver, kidney, or gallbladder • mental health problems affects your breathing problems • adrenal gland or thyroid
- Addison's disease • alcoholism gland problems

Tell your healthcare provider if you are:

- pregnant or plan to become pregnant. If you receive SUBLOCADE while pregnant, your baby may have symptoms of opioid withdrawal at birth that could be life-threatening if not recognized and treated. Talk to your healthcare provider if you are pregnant or plan to become pregnant.

breastfeeding or plan to breastfeed. SUBLOCADE can pass into your breast milk and harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with SUBLOCADE. Monitor your baby for increased drowsiness and breathing problems if you breastfeed during treatment with SUBLOCADE. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

How will I receive SUBLOCADE?

- You will receive SUBLOCADE by your healthcare provider as an injection just under the skin (subcutaneous) of your stomach (abdomen). You will receive SUBLOCADE monthly (with at least 26 days between doses).
- SUBLOCADE is injected as a liquid. After the injection, SUBLOCADE changes to a solid form called a depot. The depot may be seen or felt as a small bump under your skin at the injection site on your abdomen for several weeks. The depot will get smaller over time.
- Do not try to remove the depot.
- Do not rub or massage the injection site.
- Try not to let belts or clothing waistbands rub against the injection site.
- If you miss a dose of SUBLOCADE, see your healthcare provider to get your SUBLOCADE injection as soon as possible.

What should I avoid while being treated with SUBLOCADE?

- Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how SUBLOCADE affects you. Buprenorphine can cause drowsiness and slow reaction times. SUBLOCADE can make you sleepy, dizzy, or lightheaded. This may happen more often in the first few days after your injection and when your dose is changed.
- You should not drink alcohol or take prescription or over-the-counter medicines that contain alcohol during treatment with SUBLOCADE, because this can lead to loss of consciousness or even death.

What are the possible side effects of SUBLOCADE?

SUBLOCADE can cause serious side effects, including:

Trouble breathing. Taking other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants during treatment with SUBLOCADE can cause breathing problems that can lead to coma and death.

Sleepiness, dizziness, and problems with coordination.

- Physical dependence.
- Liver problems. Call your healthcare provider right away if you notice any of these symptoms:
- your skin or the white part of your eyes turns loss of appetite yellow (jaundice) pain, aching, or tenderness on the right side of • dark or "tea-colored" urine your stomach area light colored stools (bowel movements)

Your healthcare provider should do blood tests to check your liver before you start and during treatment with SUBLOCADE.

- Allergic reaction. You may have a rash, hives, swelling of your face, wheezing, low blood pressure, or loss of consciousness. Call your healthcare provider or get emergency help right away.

Opioid withdrawal. Call your healthcare provider right away if you get any of these symptoms:

- shaking goose bumps • sweating more than normal diarrhea • feeling hot or cold more than normal vomiting • runny nose muscle aches watery eyes
- Decrease in blood pressure. You may feel dizzy when you get up from sitting or lying down.
- The most common side effects of SUBLOCADE include:

- constipation vomiting headache increase in liver enzymes nausea tiredness • injection site itching injection site pain
- SUBLOCADE may affect fertility in males and females. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of SUBLOCADE.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

General information about SUBLOCADE

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your doctor or pharmacist for information that is written for healthcare professionals.

What are the ingredients in SUBLOCADE?

Active ingredient: buprenorphine

ATRIGEL' delivery system: biodegradable 50:50 poly(DL-lactide-co-glycolide) polymer and a biocompatible solvent, Nmethyl-2-pyrrolidone (NMP).

Manufactured for Indivior Inc., North Chesterfield, VA 23235 by AMRI, Burlington, MA 01803

For more information, go to www.SUBLOCADE.com or call 1-877-782-6966.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: 03/2021