

**UC Riverside, School of Medicine Policies and Procedures****Policy Title:** Sublocade Medication Management**Policy Number:** 950-03-023

<b>Responsible Officer:</b>	Chief Medical Officer
<b>Responsible Office:</b>	Clinical Affairs
<b>Origination Date:</b>	September, 2022
<b>Date of Revision:</b>	January, 2023
<b>Scope:</b>	UCR Health Clinical Practice Sites Certified by FDA to Administer Sublocade

**I. Policy Summary**

This policy provides guidelines for compliance with FDA approved risk evaluation and mitigation strategies (REMS) program for Sublocade (buprenorphine extended release) injection for subcutaneous use at UCR health clinical practice sites Sublocade certified by FDA.

**II. Responsibilities**

UCR Health clinical practice sites operational leadership and providers who administer Sublocade will ensure that the site is certified for the Sublocade REMS program. Notify UCR compliance and FDA of changes in authorized representative. Clinic managers and providers will follow FDA REMS and this policy to ensure safe delivery of medication.

**III. Policy Text<sup>i ii</sup>****A. Sublocade REMS program requirements**

1. Sublocade is available only through a restricted distribution program, all healthcare settings and pharmacies dispensing and administering this drug must be certified for the Sublocade REMS program.
2. Providers and clinic managers must obtain Sublocade through a restricted distribution program.
3. Sublocade should never be dispensed directly to any patient.
4. Report all suspected adverse reactions to FDA MedWatch program.
5. The Clinic Manager will maintain records of shipments of Sublocade received and dispensing information including patient name, dose, number of devices, and date administered for 10 years.
6. Clinics will comply with audits related to this FDA requirements.

**B. Indications**

1. Sublocade is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a buprenorphine-containing product, followed by dose adjustment for a minimum of 7 days.
2. Sublocade should be used as part of a complete treatment plan that includes counseling and psychosocial support.

**C. Medication ordering**

1. Sublocade is available in a prefilled syringe with dosage strengths of 100 mg/0.5 mL and 300 mg/1.5 mL buprenorphine.
2. Consider the list of potential clinically significant drug interactions with Sublocade.
  - a) Benzodiazepines and other CNS depressants.
  - b) CYP3A4 inhibitors (Macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole), protease inhibitors (e.g., ritonavir))
  - c) CYP3A4 inducers (Rifampin, carbamazepine, phenytoin, phenobarbital)
  - d) Antiretrovirals - Non-nucleoside reverse transcriptase inhibitors (Efavirenz, nevirapine, etravirine, delavirdine)
  - e) Antiretrovirals - Protease inhibitors (Atazanavir, ritonavir)
  - f) Antiretrovirals - Nucleoside reverse transcriptase inhibitors
  - g) Serotonergic drugs
  - h) Monoamine Oxidase Inhibitors (MAOIs)
  - i) Muscle relaxants
  - j) Diuretics
  - k) Anticholinergic drugs
3. Before first dose: Please refer to the most current recommendation on induction/stabilization period prior initiation of Sublocade treatment through NIH: NLM, DailyMed: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6189fb21-9432-45f8-8481-0bfaf3ccde95>

#### **D. Medication storage**

1. Sublocade is a Schedule III drug product dispensed directly to the healthcare provider.
2. Sublocade cannot be dispensed to the patient. It cannot be distributed, transferred, loaned or sold to other individuals.
3. Once Sublocade is delivered for a specific patient, it should be kept in a secure, locked refrigerator in the clinic at 2 - 8°C (35.6 - 46.4°F).
4. 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.
5. Discard Sublocade if left at room temperature for longer than 7 days.

#### **E. Patient preparation**

1. Review Sublocade safety information with patient.
2. Addendum One is a sample of the medication guide for providers to review with patients. Providers can retrieve the most current Sublocade patient medication guide through NIH: NLM, DailyMed: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6189fb21-9432-45f8-8481-0bfaf3ccde95>

#### **F. Medication preparation and administration**

1. Sublocade is for abdominal subcutaneous injection only. Do not inject intravenously, intramuscularly, or intradermally.
2. Only healthcare providers can prepare and administered Sublocade.
3. Please read the instructions carefully before handling the product.
4. As a universal precaution, always wear gloves.

5. 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 their injection. Attached needle prior administration.
6. Verify patient identity prior administered the medication.
7. Post administration, syringes should be properly disposed following UCR procedure.

**G. Monitoring, discharge, and documentation**

1. Provider will monitor patient for immediate life-threatening side effects.
2. Instruct patients not to engage in potentially hazardous activities requiring complete mental alertness and motor coordination.
3. Provider will document
  - a) medication dosage given, route, site, date and time of administration.
  - b) patient’s response to medication
  - c) unexpected side effects or adverse drug reaction.
4. Contact UCR Compliance office for any suspected adverse reactions that need to be reported to FDA MedWatch program.


**IV. Related Information**

Addendum 1: Patient safety information sample


**V. Revision History: January 2023**

Approvals:

COMPLIANCE COMMITTEE (01/23/2023)

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2/2/2023 | 12:45 PM PST  
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2/2/2023 | 7:06 PM PST  
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 DATE

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<sup>i</sup> U.S. Food & Drug Administration Drug Database: REMS sublocade healthcare provider letter, 2019, November (cited, 2022, September 30). Available from:

[https://www.accessdata.fda.gov/drugsatfda\\_docs/rems/Sublocade\\_2021\\_09\\_30\\_Healthcare\\_Provider\\_REMS\\_Letter.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/rems/Sublocade_2021_09_30_Healthcare_Provider_REMS_Letter.pdf)

<sup>ii</sup> National institute of health, National library of medicine: Daily med Sublocade, 2022, June (cited, 2022, September 30). Available

from: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6189fb21-9432-45f8-8481-0bfaf3ccde95>

**ADDENDUM 1:** A sample of the medication guide for you to review with your patient. Providers, please retrieve the most current Sublocade patient medication guide through NIH: NLM, DailyMed: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6189fb21-9432-45f8-8481-0bfaf3ccde95>

## 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 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

- have blurred vision
- have slurred speech
- are breathing slower than normal
- cannot think well or clearly

**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) buprenorphine-containing 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<sup>®</sup> 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:**

- |  |  |   |
|--|--|---|
| <ul style="list-style-type: none"> <li>• trouble breathing or lung problems</li> <li>• a curve in your spine that affects your breathing</li> <li>• Addison's disease</li> </ul> | <ul style="list-style-type: none"> <li>• an enlarged prostate (men)</li> <li>• problems urinating</li> <li>• liver, kidney, or gallbladder problems</li> <li>• alcoholism</li> </ul> | <ul style="list-style-type: none"> <li>• a head injury or brain problem</li> <li>• mental health problems</li> <li>• adrenal gland or thyroid gland problems</li> </ul> |
|--|--|---|

**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 yellow (jaundice)
- dark or “tea-colored” urine
- light colored stools (bowel movements)

- loss of appetite
- pain, aching, or tenderness on the right side of your stomach area
- nausea

- 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
- sweating more than normal
- feeling hot or cold more than normal
- runny nose
- watery eyes

- goose bumps
- diarrhea
- vomiting
- muscle aches

- **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
- headache
- nausea
- injection site itching

- vomiting
- increase in liver enzymes
- tiredness
- 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<sup>®</sup> delivery system: biodegradable 50:50 poly(DL-lactide-co-glycolide) polymer and a biocompatible solvent, **N**-methyl-2-pyrrolidone (NMP).

Medication Guide for patients retrieved on September 30, 2022 from NIH: NLM, DailyMed:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6189fb21-9432-45f8-8481-0bfaf3ccde95>

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