

Long-Acting Buprenorphine Products Tip Sheet

Overview of Long-Acting Buprenorphine Products for Opioid Use Disorder (OUD) in the United States

	Monthly Injection (Sublocade)	Weekly and Monthly Injection (Brixadi)	6 month implant (Probuphine)
Approval	Yes	Currently under review by FDA	Withdrawn from the market in October 2020
Indications	Adults with moderate to severe opioid use disorder (OUD), tolerating sublingual buprenorphine at 8-24 mg/day for at least 7 days. Counseling and psychological support should be part of treatment plan.	Adults with moderate to severe OUD, initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. Treatment OUD within framework of medical, psychological and social treatment.	N/A
Medication administration	Abdomen – subcutaneous (SC) Administered only by healthcare providers	Abdomen, arm, leg, buttock – SC Administered only by healthcare providers	N/A
Dosing	Monthly (100mg, 300mg)	Weekly (8mg, 16mg, 24mg, 32mg) Monthly (64 mg, 96mg, 128mg)	N/A
Refrigeration required	Yes – brought to room temperature prior to administration	No	N/A
REMS required	Yes	Yes	N/A
Adverse Drug Reactions	Headache, nausea, constipation, and vomiting, injection site reactions, fatigue and elevated liver function enzymes	Headache, nausea, constipation, and vomiting, injection site reactions, nasopharyngitis and urinary tract infections	N/A
Cost	\$1108.31 (100mg/0.5ml) \$1108.03 (300mg/1.5ml)	N/A	N/A

In order to support access to individualized medication assisted treatment options for OUD in Indian Country, long-acting formulations of buprenorphine have been added to the [IHS National Core Formulary](#). The IHS National Pharmacy & Therapeutics Committee [Formulary Brief: Update: MAT for Opioid Use Disorder](#) can provide additional information.

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How to Obtain Sublocade

The Sublocade product is available to order through McKesson 3 days after required REMS enrollment from the ordering facility.

Sublocade REMS Requirements

What is the SUBLOCADE REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. **Sublocade is intended for abdominal subcutaneous injection only by a healthcare provider.** Sublocade is available only through a restricted distribution program called the SUBLOCADE REMS Program because of **the risk of serious harm or death that could result from intravenous self-administration.**

How do healthcare settings and pharmacies receive and store sublocade?

1. Be certified in the SUBLOCADE REMS Program.
2. Designate an “authorized representative” to complete the **SUBLOCADE REMS Program [Healthcare Setting and Pharmacy Enrollment Form](#)** and submit it to the SUBLOCADE REMS Program for certification.
 - To enroll online, please go to www.SUBLOCADEREMS.com
 - For a step-by-step guide on enrollment read the Sublocade REMS tip sheet
 - **Important Note:** For DEA number enter facility DEA and NOT provider DEA
3. Establish processes and procedures to verify that sublocade is dispensed directly to a healthcare provider. **Sublocade should never be dispensed directly to a patient.**
4. Train staff involved in the dispensing of sublocade, to ensure that it is dispensed directly to a healthcare provider.

How should Sublocade be stored?

Store refrigerated. Once outside the refrigerator, this product may be stored in its original packaging at room temperature for up to seven (7) days prior to administration. Discard if left at room temperature for longer than 7 days.

Where can I find more information about the SUBLOCADE REMS Program?

- Visit the [Sublocade REMS FDA website](#) to access the following materials:
 - *Fact Sheet*
 - *REMS Document*
 - *Healthcare Provider REMS Letter*
 - *REMS Full Information*
 - *Healthcare Setting and Pharmacy Enrollment Form*
 - *REMS Program Website*
- Visit www.SUBLOCADEREMS.com to access the following materials:
 - *Prescribing Information*
 - *Medication Guide*
- Contact the SUBLOCADE REMS Program at 1-866-258-3905 for SUBLOCADE REMS materials and for additional information about the SUBLOCADE REMS Program.