

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

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 the benefits of the drug outweigh its risks. **SUBLOCADE is administered only by subcutaneous injection by a healthcare provider** and is only available through a restricted distribution program called the SUBLOCADE REMS. **SUBLOCADE must never be dispensed directly to the patient and must only be administered by a healthcare professional.** The goal of the REMS is to mitigate **the risk of serious harm or death that could result from intravenous self-administration.**

SUBLOCADE REMS Requirements



PRESCRIBER

1. Prescribers are **NOT required to be certified** in the SUBLOCADE REMS to prescribe SUBLOCADE.
2. Prescribers can obtain SUBLOCADE for a specific named patient's scheduled appointment by writing a prescription and sending it to a REMS-certified pharmacy. The REMS-certified pharmacy coordinates delivery to the prescriber or the practitioner administering SUBLOCADE with the patient's appointment date.
3. Prescribers that intend to keep a supply of SUBLOCADE in stock at their healthcare setting and obtain SUBLOCADE from a distributor, **must certify** their healthcare setting or practice in the SUBLOCADE REMS. See below.



HEALTHCARE SETTING* AND PHARMACY

Any healthcare setting* (including a prescriber office) or pharmacy that intends to keep a supply of SUBLOCADE in stock and order SUBLOCADE directly from an authorized distributor **must be certified** in the SUBLOCADE REMS prior to purchasing/dispensing SUBLOCADE.



How does a healthcare setting* or pharmacy become certified?

To become certified in the SUBLOCADE REMS, healthcare settings and pharmacies must:

1. Designate an Authorized Representative
2. Agree to:
 - Train all relevant staff at each dispense location involved in dispensing the drug directly to a healthcare provider, to ensure that the drug is not dispensed directly to a patient.
 - Establish processes and procedures to verify that SUBLOCADE is dispensed directly to a healthcare provider. **Do not dispense SUBLOCADE directly to a patient.**
 - Establish processes and procedures to notify the healthcare provider not to dispense SUBLOCADE directly to patients.
3. Complete the REMS enrollment process by filling out and signing the *Healthcare Setting and Pharmacy Enrollment Form*, which may be obtained at www.sublocaderems.com

*Examples of healthcare settings include, but are not limited to: group practice, independent practice, institution, Department of Defense (DoD) facility, outpatient clinic, hospital, Veterans Administration (VA) facility, opioid treatment program (OTP), closed healthcare system.

SUBLOCADE must never be dispensed directly to a patient.

Does a prescriber that wants to have SUBLOCADE administered to a named patient at their scheduled appointment need to certify? How do prescribers obtain SUBLOCADE?

Prescribers do not need to certify in the REMS. Prescribers should write a prescription as usual for their patient and send the prescription to a REMS-certified pharmacy. REMS-certified pharmacies can be found on the REMS website (www.sublocaderems.com) or by calling 1-866-258-3905. The pharmacy will coordinate delivery with the patient's scheduled appointment and deliver to the prescriber or the administering practitioner designated by the prescriber. **SUBLOCADE is never dispensed directly to the patient and must only be administered by a healthcare professional.**

Does a prescriber that wants to keep a bulk supply of SUBLOCADE in stock at their office need to certify? How do prescribers obtain SUBLOCADE?

The prescriber's office/healthcare setting must certify in the REMS and obtain SUBLOCADE through an authorized distributor.

How should SUBLOCADE be stored?

SUBLOCADE should be kept in a secure place per state and federal regulations and stored refrigerated according to the prescribing information. Once outside the refrigerator, this product may be stored in its original packaging at room temperature for up to 12 weeks prior to administration. Discard SUBLOCADE if left at room temperature for longer than 12 weeks.

Where can I find more information about the SUBLOCADE REMS?

You may obtain additional information about the SUBLOCADE REMS by:

Visiting www.SUBLOCADEREMS.com to access the following:

- ***SUBLOCADE REMS Healthcare Setting and Pharmacy Enrollment Form***
- ***SUBLOCADE REMS Dear Healthcare Provider Letter***
- ***Prescribing Information***
- ***Medication Guide***
- ***REMS-certified Pharmacy Locator***
- ***List of Authorized Distributors***

Contacting the SUBLOCADE REMS at 1-866-258-3905 for SUBLOCADE REMS materials and for additional information about the SUBLOCADE REMS.

Visiting <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>.

Calling Indivior's Medical Information line at **1-877-782-6966**.

**Sublocade**[®]
(buprenorphine extended-release)
injection for subcutaneous use [®]

