Risk Evaluation and Mitigation Strategy (REMS)

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.**

What are the SUBLOCADE REMS program requirements?

- All healthcare settings and pharmacies that dispense SUBLOCADE must be certified in the SUBLOCADE REMS program
- Healthcare providers, healthcare settings, and pharmacies must obtain SUBLOCADE through a restricted distribution program
- **SUBLOCADE should never be dispensed directly to a patient.**

Which healthcare settings MUST BE certified in the SUBLOCADE REMS program?

All healthcare settings and pharmacies that dispense SUBLOCADE must be certified. Examples of healthcare settings include: group practice, independent practice, institution, Department of Defense (DoD) facility, outpatient clinic, hospital, Veterans Administration (VA) facility, opioid treatment program (OTP), closed healthcare system, other healthcare setting.

How does my healthcare setting or pharmacy become certified in the SUBLOCADE REMS program?

1. **Get Started here**

   Designate an **authorized representative.** The authorized representative will ensure that each dispensing location that meets the REMS requirements will be permitted to purchase, receive, and dispense SUBLOCADE. The certification will be confirmed prior to shipping SUBLOCADE.

2. **Review REMS Materials**

   Review the SUBLOCADE REMS Program materials, including ***SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE***, the Prescribing Information, and the Medication Guide.

3. **Complete the Enrollment Process**

   Complete, sign, and submit the ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form.***

   Only one (1) form is needed per healthcare setting. A pharmacy is covered under their healthcare setting's enrollment in the SUBLOCADE REMS Program.

   The ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form*** contains three sections:

   - "Authorized Representative Signature" section
   - "Authorized Representative Information" section
   - "Healthcare Setting Information" section

   For the initial enrollment, all three sections noted above must be submitted. To add an additional healthcare setting after the initial enrollment, you may submit just the "Healthcare Setting Information" section for each dispensing site where SUBLOCADE will be shipped within your healthcare system.

   If a designated authorized representative changes, the new authorized representative must complete and sign a new ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form***, including a "Healthcare Setting Information" section for each healthcare setting with which he/she is now affiliated.

   The ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form*** may be completed via one of the following enrollment options below:

   - To enroll **online**, please **click here**.
   - For enrollment via **FAX**, please complete all required fields on the form and one "Healthcare Setting Information" section for each dispensing site, and fax the section(s) to 1-866-823-9549.
   - For enrollment via **E-mail**, please complete all required fields on the form and one "Healthcare Setting Information" section for each dispensing site, and email the section(s) to **certify@SublocadeREMS.com**.
   - For enrollment via **mail**, please complete all required fields on the form and one "Healthcare Setting Information" section for each dispensing site, and mail the section(s) to SUBLOCADE REMS Program, 200 Pinecrest Plaza, Morgantown, WV 26505-8065.

4. **Implement the REMS Program**

   - Establish processes and procedures to verify that SUBLOCADE is dispensed directly to a healthcare provider for administration to a patient. **SUBLOCADE should never be dispensed directly to a patient.**
   - Implement the necessary staff training and processes to comply with the SUBLOCADE REMS Program requirements.

How can certified healthcare settings obtain SUBLOCADE for potential patients?

In advance of the patient's appointment, order SUBLOCADE from an authorized distributor. SUBLOCADE should be administered by a healthcare professional in your office or clinic directly to the patient. **SUBLOCADE should never be dispensed directly to a patient.**

How can DATA 2000-waivered prescribers obtain SUBLOCADE for their patients?

Prescribers who are DATA 2000-waivered can obtain SUBLOCADE for their patients in two ways.

1. Through a certified pharmacy for a named patient:

   In advance of the patient's appointment, send a prescription for your named patient to a certified pharmacy. The certified pharmacy will send SUBLOCADE to you to administer it directly to that patient. SUBLOCADE should never be dispensed directly to the patient. It should be administered by a healthcare professional in your office or clinic. Your healthcare setting **does not need to be certified** in the SUBLOCADE REMS Program for you to administer SUBLOCADE to an individual named patient obtained through a certified pharmacy. A list of certified pharmacies is appended to each mailing of the ***SUBLOCADE REMS Program Dear Healthcare Provider Letter***. Additionally, the current list may be obtained on the SUBLOCADE REMS website or from the SUBLOCADE REMS Program at 1-866-258-3905. **SUBLOCADE should never be dispensed directly to a patient.**

2. By ordering SUBLOCADE directly through a distributor:

   To order SUBLOCADE through a distributor, the healthcare setting in which you practice must first become certified.

How should SUBLOCADE be stored?

Once SUBLOCADE is delivered for a named patient or is obtained for a healthcare setting's bulk supply, it should be kept in a secure place per state and federal regulations. 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 SUBLOCADE if left at room temperature for longer than seven (7) days.

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

- Review the following materials:
  - ***SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form***
  - ***SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE***
  - ***SUBLOCADE REMS Program Dear Healthcare Provider Letter***
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  - ***Medication Guide***
- Contact the SUBLOCADE REMS Program at 1-866-258-3905 for REMS materials and for additional information about the SUBLOCADE REMS Program.
- Visit the REMS@FDA website at: **https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm**.
- Call Indivior's Medical Information line (1-877-782-6966).

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Indication

SUBLOCADE is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product, 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.

Reporting Adverse Events

You are encouraged to report negative side effects to the FDA. Healthcare providers should report all cases of intravenous administration and suspected adverse events associated with SUBLOCADE to the FDA at 1-800-FDA-1088 or online at **www.fda.gov/medwatch/report.htm** or to Indivior at 1-877-782-6966 or **PatientSafetyNA@indivior.com**.

Materials for SUBLOCADE REMS:

- **SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form**
- **SUBLOCADE REMS Program Dear Healthcare Provider Letter**
- **SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE**

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