



SUBLOCADE REMS Program Fact Sheet

How to Obtain SUBLOCADE

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?

Any pharmacy that dispenses SUBLOCADE as well as any healthcare setting* (including a prescriber office) that purchases SUBLOCADE from a distributor must be certified prior to dispensing/purchasing SUBLOCADE. Prescriber offices that only order SUBLOCADE from a certified pharmacy for a specific patient are exempt from certification.

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 specific 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.

*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 can healthcare settings* obtain SUBLOCADE for potential patients?

To receive and store a supply of SUBLOCADE for a healthcare setting, all healthcare settings and pharmacies that dispense SUBLOCADE* must:

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.
3. Train relevant staff involved in the dispensing of SUBLOCADE, to ensure that it is dispensed directly to a healthcare provider.
4. Establish processes and procedures to verify that SUBLOCADE is dispensed directly to a healthcare provider. **SUBLOCADE should never be dispensed directly to a patient.**

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?

- Visit www.SUBLOCADEREMS.com to access the following materials:
 - **SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form**
 - **SUBLOCADE REMS Program Dear Healthcare Provider Letter**
 - **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.
- 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).

*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.

