



FDA-REQUIRED REMS SAFETY INFORMATION

WARNING: RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS ADMINISTRATION; SUBLOCADE RISK EVALUATION AND MITIGATION STRATEGY

- Serious harm or death could result if administered intravenously. SUBLOCADE forms a solid mass upon contact with body fluids and may cause occlusion, local tissue damage, and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.
- Because of the risk of serious harm or death that could result from intravenous self-administration, SUBLOCADE is only available through a restricted program called the SUBLOCADE REMS Program. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.

March 1, 2018

Dear Healthcare Provider:

The purpose of this letter is to inform you about **the risk of serious harm or death that could result from intravenous self-administration of SUBLOCADE and its restricted distribution program**. The FDA has determined that a **Risk Evaluation and Mitigation Strategy (REMS)** is necessary to ensure that the benefits of SUBLOCADE outweigh this serious risk.

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**. **SUBLOCADE is intended for abdominal subcutaneous injection only by a healthcare provider.**

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.**

Please see the attached non-promotional **SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE**, reviewed by the FDA, for information about **how your healthcare setting or pharmacy can obtain SUBLOCADE**.

Please visit www.SUBLOCADEREMS.com for information about **how your healthcare setting or pharmacy can certify** in the SUBLOCADE REMS Program.





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 Fact Sheet: How to Obtain SUBLOCADE**
 - **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/remis/index.cfm>.
- Call Indivior's Medical Information line (1-877-782-6966).

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.

Sincerely,

A handwritten signature in black ink, appearing to read "Baher Mankabady", enclosed in a simple black oval.

Baher Mankabady, MD
Vice President, Global Patient Safety

Indivior Inc.

Enclosed:

SUBLOCADE REMS Program Fact Sheet: How to Obtain SUBLOCADE

List of SUBLOCADE REMS Program-certified Pharmacies

Note: 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.

