

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. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.

Dear Healthcare Provider:

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

Per the SUBLOCADE REMS, SUBLOCADE is only available through a restricted distribution program.

SUBLOCADE REMS requirements:

- Any pharmacy or healthcare setting (including a prescriber office) that intends to store a supply of and order SUBLOCADE directly from an authorized distributor **must be certified** in the SUBLOCADE REMS prior to purchasing / dispensing SUBLOCADE.
NOTE: Certification in the SUBLOCADE REMS is **not required** if a healthcare setting intends to only obtain SUBLOCADE from a REMS-certified pharmacy for administration by a practitioner at a **specific named patient's scheduled appointment**. The REMS-certified pharmacy will coordinate delivery to the administering practitioner with the patient's appointment.
 - Healthcare providers are **not required** to certify in the REMS to prescribe SUBLOCADE.
- **SUBLOCADE must never be dispensed directly to a patient.**

Enclosed with this letter is the **SUBLOCADE REMS Fact Sheet: How to Obtain SUBLOCADE**, which provides an overview of the REMS including information about **how your healthcare setting or pharmacy can obtain SUBLOCADE** and the **List of SUBLOCADE REMS-certified Pharmacies**.

Please visit www.SUBLOCADEREMS.com or contact the SUBLOCADE REMS at 1-866-258-3905 for SUBLOCADE REMS materials and for additional information about **how your healthcare setting or pharmacy can become certified** in the SUBLOCADE REMS. For medical related questions, please contact Indivior's Medical Information Unit at 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 single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.

SUBLOCADE should be used as part of a complete treatment plan that includes counseling and psychosocial support.

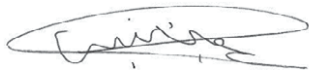
SUBLOCADE Storage

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.

Reporting Adverse Events

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

Sincerely,



Baher Mankabady, MD
Senior Vice President, Global Medical Safety
Indivior Inc.

Enclosed:

SUBLOCADE REMS Fact Sheet: How to Obtain SUBLOCADE

List of SUBLOCADE REMS-certified Pharmacies


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

 **INDIVIOR[®]**