Risk Evaluation and Mitigation Strategy (REMS) Document
SUBLOCADE (buprenorphine extended-release) REMS Program

I. Administrative Information

Application Number: NDA 209819
Application Holder: Indivior Inc.
Initial REMS Approval: [11/2017]
Most Recent REMS Update: [03/2018]

II. REMS Goal

The goal of the SUBLOCADE REMS is to mitigate the risk of serious harm or death that could result from intravenous self-administration by:

- Ensuring healthcare settings and pharmacies are certified and only dispense SUBLOCADE directly to a healthcare provider for administration by a healthcare provider

III. REMS Requirements

Indivior must ensure that healthcare settings, pharmacies, and wholesalers/distributors comply with the following requirements:

1. Healthcare settings and pharmacies that dispense SUBLOCADE must:

   - Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting or pharmacy.
   - Have the authorized representative enroll in the REMS Program by completing the Healthcare Setting and Pharmacy Enrollment Form and submitting it to the REMS Program.
   - Train all relevant staff involved in dispensing that the drug must be dispensed directly to a healthcare provider for administration by a healthcare provider, and the drug must not be dispensed to the patient.
   - Establish processes and procedures to verify SUBLOCADE is dispensed directly to a healthcare provider and the drug is not dispensed to the patient.
   - Establish processes and procedures to notify the healthcare provider not to dispense the drug directly to patients.
   - Verify that SUBLOCADE is dispensed directly to a healthcare provider and the drug is not dispensed to the patient.
   - Notify the healthcare provider not to dispense the drug directly to patients.
To maintain certification to dispense

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<td>8.</td>
<td>Have a new authorized representative enroll in the REMS Program by completing the Healthcare Setting and Pharmacy Enrollment Form if the authorized representative changes.</td>
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At all times

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<td>9.</td>
<td>Not distribute, transfer, loan or sell SUBLOCADE.</td>
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<td>10.</td>
<td>Maintain records of all processes and procedures including compliance with those processes and procedures.</td>
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<td>11.</td>
<td>Comply with audits by Indivior Inc. or a third party acting on behalf of Indivior to ensure that all processes and procedures are in place and are being followed for the SUBLOCADE REMS Program.</td>
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### 2. Wholesalers/Distributors that distribute SUBLOCADE must:

- **To be able to distribute**
  
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<tr>
<td>1.</td>
<td>Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings and pharmacies.</td>
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<td>2.</td>
<td>Train all relevant staff involved in distributing SUBLOCADE on the process and procedures to verify the healthcare settings and pharmacies are certified.</td>
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At all times

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<td>3.</td>
<td>Distribute only to certified healthcare settings and pharmacies.</td>
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<td>4.</td>
<td>Maintain and submit records of all shipments of SUBLOCADE to Indivior.</td>
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<td>5.</td>
<td>Comply with audits carried out by Indivior or a third party acting on behalf of Indivior to ensure that all processes and procedures are in place and are being followed.</td>
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To inform healthcare providers about the REMS Program and the risks and safe use of SUBLOCADE, Indivior must disseminate REMS communication materials according to the table below:

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<th>Target Audience</th>
<th>Communication Materials &amp; Dissemination Plans</th>
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<td>All prescribers certified to treat opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA 2000); all pharmacies authorized by DEA to handle schedule III controlled substances on a national mailing list from the National Technical Information Service; all Opioid Treatment Programs certified under 42 CFR 8</td>
<td>REMS Letter: Healthcare Provider REMS Letter with attachment: Fact Sheet: How to Obtain SUBLOCADE</td>
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<td>1. Mail within 60 calendar days of the date SUBLOCADE is first commercially distributed and again 6 months later.</td>
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<td></td>
<td>2. eMail within 60 calendar days of the date SUBLOCADE is first commercially distributed and again 6 months later.</td>
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<td>3. Make available via a link from the SUBLOCADE REMS Program Website.</td>
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<td>4. Disseminate through professional societies and request the content be provided to their members.</td>
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<td></td>
<td>5. Disseminate at Professional Meetings for 1 year from the date SUBLOCADE is first commercially distributed.</td>
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| All prescribers certified to treat opioid dependence under | REMS Letter: Healthcare Provider REMS Letter with attachment: Fact Sheet: How to Obtain SUBLOCADE |
To support REMS Program operations, Indivior must:

1. Establish and maintain a REMS Program website, www.SUBLOCADEREMS.com. The REMS Program website must include the capability to complete healthcare setting and pharmacy certification online, the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website.

2. Make the REMS Program website fully operational and all REMS materials available through website and call center by the date SUBLOCADE is first commercially distributed.

3. Establish and maintain a REMS Program call center for REMS participants at 1-866-258-3905.

4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the SUBLOCADE REMS Program.

5. Ensure healthcare settings and pharmacies are able to enroll by fax, mail, email, and online.

6. Provide Healthcare Provider REMS Letter, Fact Sheet: How to Obtain SUBLOCADE, Healthcare Setting and Pharmacy Enrollment Form and the Prescribing Information to REMS participants who (1) attempt to dispense SUBLOCADE and are not yet certified or (2) inquire about how to become certified.

7. Notify healthcare settings and pharmacies, confirming certification, within 7 calendar days after they become certified in the REMS Program.

8. Provide wholesalers/distributors access to the database of certified healthcare settings and pharmacies.

To ensure REMS participants’ compliance with the REMS Program, Indivior must:

9. Verify annually that the authorized representative’s name and contact information correspond to those of the current designated authorized representative for the certified healthcare setting or pharmacy. If different, the healthcare setting and pharmacy must be required to re-certify with a new authorized representative.

10. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: SUBLOCADE distribution and dispensing; certification of pharmacies and healthcare settings; and audits of REMS participants.

11. Establish a plan for addressing non-compliance with REMS Program requirements.

12. Monitor healthcare settings, pharmacies, and wholesalers/distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.
13. Audit 25 healthcare settings at 12 months from the date the drug is first commercially distributed and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. To be audited, healthcare settings must have received at least one shipment of SUBLOCADE in the past 12 months and not have been previously audited in the past 3 years.

14. Audit pharmacies no later than 90 calendar days after the pharmacy receives its first shipment, and annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.

15. Audit wholesalers/distributors no later than 90 calendar days after they become authorized or from the date SUBLOCADE is first commercially distributed (whichever is later), and annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.

16. Take reasonable steps to improve implementation of and compliance with the requirements in the SUBLOCADE REMS Program based on monitoring and evaluation of the SUBLOCADE REMS Program.

IV. REMS Assessment Timetable

Indivior must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS (11/30/2017). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Indivior must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the SUBLOCADE REMS and are appended:

**Enrollment Forms:**

Healthcare Setting and Pharmacy:

1. Healthcare Setting and Pharmacy Enrollment Form

**Communication Materials**

2. Healthcare Provider REMS Letter
3. Fact Sheet: How to Obtain SUBLOCADE

**Other Materials**

4. REMS Program Website
SUBLOCADE REMS Program

Healthcare Setting and Pharmacy Enrollment Form

Instructions:

SUBLOCADE is only available through the SUBLOCADE Risk Evaluation and Mitigation Strategy (REMS) Program. Before SUBLOCADE is provided, healthcare settings or pharmacies must:

1. Designate an authorized representative.
2. Complete and sign this SUBLOCADE REMS Program Healthcare Setting and Pharmacy Enrollment Form and submit it to the REMS Program.
3. Agree to train all relevant staff at each dispensing location involved in dispensing the drug directly to a healthcare provider, to ensure that the drug is not dispensed directly to a patient.
4. Agree to verify that SUBLOCADE is dispensed directly to a healthcare provider. Do not dispense SUBLOCADE directly to a patient.
5. Agree to notify the healthcare provider not to dispense directly to patients.

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 – page 2
- “Authorized Representative Information” section – page 3
- “Healthcare Setting Information” section – page 4

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 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.

Enrollment can be done via the online portal, fax, email, or mail.

- To enroll online, please go to www.SUBLOCADEREMS.com.
- 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.

For questions regarding the SUBLOCADE REMS Program or how to enroll, visit www.SUBLOCADEREMS.com or contact the SUBLOCADE REMS Program at 1-866-258-3905.
Authorized Representative Responsibilities

I am the authorized representative designated by my healthcare setting or pharmacy to coordinate the activities of the SUBLOCADE REMS Program. On behalf of the healthcare setting or pharmacy, I agree that we will comply with the following program requirements:

• Become certified with the SUBLOCADE REMS Program to order SUBLOCADE.
• Understand that there is a risk of serious harm or death that could result from intravenous self-administration. **Do not dispense SUBLOCADE directly to a patient.**
• Establish processes and procedures to verify SUBLOCADE is dispensed to a healthcare provider, and SUBLOCADE is not dispensed to a patient.
• Ensure that all relevant staff involved in dispensing SUBLOCADE are trained that SUBLOCADE must be dispensed directly to a healthcare provider for administration by a healthcare provider, and that SUBLOCADE must not be dispensed directly to a patient.
• Establish processes and procedures to notify the healthcare provider not to dispense directly to patients. Notifications may be accomplished through a variety of mechanisms based on the healthcare setting. Phone calls, an auxiliary label printed automatically and affixed to the dispensed prescription, or reminders in the electronic medical record are potential mechanisms to communicate the alert.
• Establish processes and procedures to not distribute, transfer, loan, or sell SUBLOCADE.
• Maintain records of all processes and procedures including compliance with those processes and procedures.
• Comply with audits by Indivior Inc. or a third party acting on behalf of Indivior to ensure that all processes and procedures are in place and are being followed for the SUBLOCADE REMS Program.
• Ensure each dispensing site location has policies and procedures and will provide the following information (site name, DEA number, address, phone, fax, email, and primary point of contact if not the authorized representative) to the SUBLOCADE REMS Program, to enable those sites to purchase, receive, and dispense SUBLOCADE.

I understand that this enrollment applies to my healthcare setting(s) or pharmacy for which I am the designated authorized representative.

__________________________________________
Healthcare Setting or Pharmacy Authorized Representative Signature*

__________________________________________
Date (MM/DD/YYYY)*
AUTHORIZED REPRESENTATIVE INFORMATION

(*REQUIRED FIELDS)

Credentials*:
- [ ] Pharmacist
- [ ] Nurse Practitioner
- [ ] Practice Manager
- [ ] Other
- [ ] Physician
- [ ] Nurse
- [ ] Physician Assistant

First Name* (please print)  MI  Last Name* (please print)

Position/Title  Email Address* or Fax Number*  Phone Number* Ext

Preferred Method of Communication for Correspondence* (please select one)
- [ ] Email
- [ ] Fax

Healthcare Setting or Pharmacy Authorized Representative Signature*  Date (MM/DD/YYYY)*
HEALTHCARE SETTING INFORMATION

(*REQUIRED FIELDS)

Authorized Representative Name*

Phone Number* or Fax Number* or Email Address*

Healthcare Setting Name*

DEA Number (on file with distributor account)*

Primary Point of Contact (if person is not the authorized representative)*

Address*

Address Line 2

City*       State*       ZIP*

Phone Number*       Fax Number*       or       Email Address*

Setting Type*

**Pharmacy:**
- Specialty Pharmacy
- Other ______

**Healthcare Setting:**
- 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 __________________

I am the designated authorized representative for this healthcare setting or pharmacy.

Healthcare Setting or Pharmacy Authorized Representative Signature*

Date (MM/DD/YYYY)*
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 program called the SUBLOCADE REMS Program because of the risk of serious harm or death that could result from intravenous self-administration. Healthcare settings and pharmacies that order and dispense SUBLOCADE must be certified in this program and comply with the REMS requirements.

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/rems/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,

<NAME>

<TITLE> 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.
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.
Risk Evaluation and Mitigation Strategy (REMS) Program

What is the SU/BULOCIDE 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 FDA to ensure the benefits of a drug outweigh the risks. SU/BULOCIDE is listed for the treatment of bacterial infections caused by susceptible strains of aerobic Gram-positive organisms. This product is only available through a restricted distribution program called the SU/BULOCIDE REMS Program because of the risk of serious harm in a subdose that small doses of benzyl alcohol (an inactive ingredient) in the formulation may be self-administered.

What are the SU/BULOCIDE REMS program requirements?

All healthcare settings and pharmacies that dispense SU/BULOCIDE must be certified. This includes healthcare providers, healthcare settings, and pharmacies that obtain SU/BULOCIDE through a restricted distribution program. SU/BULOCIDE should not be dispensed directly to a patient.

When healthcare settings must be certified to the SU/BULOCIDE REMS program

All healthcare settings and pharmacies that dispense SU/BULOCIDE must be certified. Examples of healthcare settings include: group practices, independent practices, institutions, Department of Defense (DoD) facilities, federal, state, local, and tribal health departments, and institutional health care systems. In some cases, a group practice or a health care setting may be certified to obtain SU/BULOCIDE for the practice or setting.

3. Review REMS Materials

Access the SU/BULOCIDE REMS Program materials, including SU/BULOCIDE REMS Program Fact Sheet: How to Obtain SU/BULOCIDE using the Password Enforcement Form.

3. Complete the Enrolment Process

Complete, sign, and submit the SU/BULOCIDE REMS Program Healthcare Setting and Pharmacy Enrollment Form:

- To enroll, please click here.

[Attach PDF]

- After completing the eForm, please complete all required fields on the form and forward the enrollment form to the SU/BULOCIDE REMS Program, c/o Indivior, Inc., 1600 Vasona Lake Drive, Suite 200, Santa Clara, CA 95054

4. Implement the REMS Program

- New healthcare settings will be notified by email of the information required to obtain SU/BULOCIDE, including if the healthcare setting is subject to third-party coverage for the information and training costs.

5. How can healthcare settings obtain SU/BULOCIDE for potential patients?

- To obtain SU/BULOCIDE for a potential patient, you must first be certified to the SU/BULOCIDE REMS Program. To be certified, you must be a healthcare setting, pharmacy, or provider who is authorized to prescribe SU/BULOCIDE.

6. How can I obtain SU/BULOCIDE for my patient?

- SU/BULOCIDE should be dispensed only by a healthcare provider who is authorized to prescribe SU/BULOCIDE.

7. How can SU/BULOCIDE be stored?

- SU/BULOCIDE must be stored at a temperature of 20° to 25°C (68° to 77°F) protected from light and moisture. SU/BULOCIDE should not be dispensed directly to a patient.

8. Where can I find more information about the SU/BULOCIDE REMS Program?

- Visit the following materials:

- SU/BULOCIDE REMS Program Healthcare Setting and Pharmacy Enrollment Form
- SU/BULOCIDE REMS Program Facts Sheet: How to Obtain SU/BULOCIDE
- SU/BULOCIDE REMS Program Healthcare Provider Letter
- Prescribing information
- Indication Guide
- Contact the SU/BULOCIDE REMS Program at 1-866-366-0494 (for REMS materials and the additional information about the SU/BULOCIDE REMS Program)
- Visit the INDIVIOR website at https://www.indivior.com/safety/su-bulocide
- Call Indivior’s Medical Information: 1-877-752-6980

- For additional information about the REMS, please visit the SU/BULOCIDE REMS Program Facts Sheet: How to Obtain SU/BULOCIDE on the INDIVIOR website at https://www.indivior.com/safety/su-bulocide

- SU/BULOCIDE should be used as part of a comprehensive treatment plan that includes counseling and psychosocial support.
Risk Evaluation

You are now leaving the SoludoseREMS.com website.

What is the SoludoseREMS Program? A REEMs is a single disease management program that establishes how health care providers, healthcare settings, and pharmacies must obtain and store SoludoseREMS labels and how the program will be conducted. SoludoseREMS should never be dispensed directly to a patient.

What are the SoludoseREMS Program requirements?
- All healthcare settings and pharmacies that dispense SoludoseREMS must be certified to use the SoludoseREMS Program.
- Health care providers, healthcare settings, and pharmacies must obtain and store SoludoseREMS labels according to the program.
- SoludoseREMS should never be dispensed directly to a patient.

What are the essential steps for being certified to the SoludoseREMS Program?
- All healthcare settings and pharmacies that dispense SoludoseREMS must be certified. All healthcare settings must complete and sign a new SoludoseREMS Program enrollment form, including a complete list of healthcare settings with which the facilities have dispensing agreements.

Complete the Enrollment Process

Complete, sign, and submit the SoludoseREMS Program Kathleen Setting and Pharmacy Enrollment Form, along with the necessary documents for your healthcare setting (e.g., a letter from the state's health agency or the SoludoseREMS Program, the Standard Operating Procedure, and the approved label).

Your enrollment will be reviewed by a SoludoseREMS representative, and you will be contacted to set up a site visit. The representative is responsible for certifying the healthcare setting's ability to store and dispense SoludoseREMS directly to a patient.

If your healthcare setting is approved, you will receive a certificate of certification. Your healthcare setting will then be connected to the SoludoseREMS Program's electronic database, allowing healthcare providers to access information on dispensing and dosing information for SoludoseREMS.

How can healthcare professionals be certified to the SoludoseREMS Program? Healthcare professionals who are certified to the SoludoseREMS Program can receive training and materials for dispensing and dosing information for SoludoseREMS, as well as access to the SoludoseREMS electronic database.

How can a drug be prescribed for a patient who has been certified to the SoludoseREMS Program? Healthcare professionals who are certified to the SoludoseREMS Program can receive training and materials for dispensing and dosing information for SoludoseREMS, as well as access to the SoludoseREMS electronic database.

How can I access the SoludoseREMS Program? Healthcare professionals who are certified to the SoludoseREMS Program can receive training and materials for dispensing and dosing information for SoludoseREMS, as well as access to the SoludoseREMS electronic database.

Use of SoludoseREMS for pain management: SoludoseREMS should be prescribed for pain management in the same manner as any other drug. It is important to review the patient's medical history and understand their pain management needs before prescribing SoludoseREMS.

How can I access the SoludoseREMS Program? Healthcare professionals who are certified to the SoludoseREMS Program can receive training and materials for dispensing and dosing information for SoludoseREMS, as well as access to the SoludoseREMS electronic database.