

# Risk Evaluation and Mitigation Strategy (REMS) Document

## BRIXADI (buprenorphine) extended-release REMS

### I. Administrative Information

Risk: Serious harm or death that could result from intravenous self-administration

Application Number: NDA 210136

Application Holder: Braeburn Inc.

Initial REMS Approval: 05/2023

Most Recent REMS Update: 03/2025

### II. REMS Goal

The goal of the BRIXADI 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 BRIXADI directly to a healthcare provider for administration by a healthcare provider.

### III. REMS Requirements

**Braeburn Inc. must ensure that healthcare settings, pharmacies, and wholesalers-distributors comply with the following requirements:**

---

#### 1. Healthcare settings and pharmacies that dispense BRIXADI must:

---

To become certified to dispense	<ol style="list-style-type: none"><li>1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting or pharmacy.</li><li>2. Have the authorized representative enroll in the REMS by completing the <a href="#">Healthcare Setting and Pharmacy Enrollment Form</a> and submitting it to the REMS.</li><li>3. 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.</li><li>4. Establish processes and procedures to verify BRIXADI is dispensed directly to a healthcare provider and the drug is not dispensed to the patient.</li><li>5. Establish processes and procedures to notify the healthcare provider not to dispense the drug directly to patients.</li></ol>
Before dispensing	<ol style="list-style-type: none"><li>6. Verify that BRIXADI is dispensed directly to a healthcare provider and the drug is not dispensed to the patient.</li><li>7. Notify the healthcare provider not to dispense the drug directly to patients.</li></ol>

---

To maintain certification to dispense	8. Have a new authorized representative enroll in the REMS by completing and submitting the <a href="#">Healthcare Setting and Pharmacy Enrollment Form</a> , if the authorized representative changes.
At all times	9. Not distribute, transfer, loan or sell BRIXADI. 10. Maintain records of all processes and procedures including compliance with those processes and procedures. 11. Comply with audits by Braeburn Inc. or a third party acting on behalf of Braeburn Inc. to ensure that all processes and procedures are in place and are being followed.

**2. Wholesalers-Distributors that distribute BRIXADI must:**

To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings and pharmacies. 2. Train all relevant staff involved in distributing BRIXADI on the process and procedures to verify the healthcare settings and pharmacies are certified.
At all times	3. Distribute only to certified healthcare settings and pharmacies. 4. Maintain and submit records of all shipments of BRIXADI to Braeburn Inc. 5. Comply with audits carried out by Braeburn Inc. or a third party acting on behalf of Braeburn Inc. to ensure that all processes and procedures are in place and are being followed.

**To inform healthcare providers about the REMS and the risks and safe use of BRIXADI, Braeburn Inc. must disseminate REMS communication materials according to the table below:**

<b>Target Audience</b>	<b>Communication Materials &amp; Dissemination Plans</b>
All healthcare providers who prescribe buprenorphine for the treatment of opioid use disorder; all pharmacies authorized by DEA to handle schedule III controlled substances; all Opioid Treatment Programs certified under 42 CFR 8	REMS Letter: <a href="#">Healthcare Provider REMS Letter</a> with attachment: <a href="#">Fact Sheet: How to Obtain BRIXADI</a> . 1. Mail within 60 calendar days of the date of the approval of the REMS and again 6 months later, or 2. eMail within 60 calendar days of the date of the approval of the REMS and again 6 months later. 3. Make available via a link from the BRIXADI REMS Website. 4. Disseminate within 60 calendar days of the date of the approval of the REMS through professional societies and request the content be provided to their members. a. The professional societies are identified in Appendix A. 5. Disseminate at Professional Meetings where Braeburn Inc. has a presence for 1 year from the date of the approval of the REMS.
All new healthcare providers who prescribe buprenorphine	REMS Letter: <a href="#">Healthcare Provider REMS Letter</a> with attachment: <a href="#">Fact Sheet: How to Obtain BRIXADI</a>

**Target Audience**

for the treatment of opioid use disorder since the last dissemination; all pharmacies authorized by DEA to handle schedule III controlled substances since the last dissemination; all Opioid Treatment Programs certified under 42 CFR 8 since the last dissemination

**Communication Materials & Dissemination Plans**

6. Mail annually from the date of the approval of the REMS, or
7. eMail annually from the date of the approval of the REMS.

**To support REMS operations, Braeburn Inc. must:**

1. Establish and maintain a REMS website, [www.BRIXADIREMS.com](http://www.BRIXADIREMS.com). The REMS 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 website. The REMS website must not link back to the promotional product website.
2. Make the REMS website fully operational and all REMS materials available through website and call center by the date BRIXADI is first commercially distributed.
3. Establish and maintain a REMS call center for REMS participants at 1-866-492-9624.
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the BRIXADI REMS.
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 BRIXADI, Healthcare Setting and Pharmacy Enrollment Form](#) and the Prescribing Information to REMS participants who (1) attempt to dispense BRIXADI 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.
8. Provide wholesalers-distributors access to the database of certified healthcare settings and pharmacies.

**To ensure REMS participants' compliance with the REMS, Braeburn Inc. 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: BRIXADI distribution and dispensing; certification of pharmacies and healthcare settings; and audits of REMS participants.
11. Establish and maintain a plan for addressing non-compliance with REMS 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 a representative sample of healthcare settings no later than 90 calendar days after the healthcare setting is certified and receives its first shipment of BRIXADI, and audit a representative sample annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.
14. Audit all pharmacies no later than 90 calendar days after the pharmacy is certified and receives its first shipment of BRIXADI, and audit a representative sample annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.
15. Audit all wholesalers-distributors no later than 90 calendar days after they become authorized, and audit all wholesalers-distributors annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.
16. Take reasonable steps to improve operations of and compliance with the requirements in the BRIXADI REMS based on monitoring and evaluation of the BRIXADI REMS.

## **IV. REMS Assessment Timetable**

Braeburn Inc. must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS (05/23/2023). 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. Braeburn Inc. 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 BRIXADI 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 BRIXADI](#)

### **Other Materials**

4. [REMS Website](#)

## **VI. Statutory Elements**

This REMS is required under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Elements to Assure Safe Use (ETASU):
  - Pharmacies and health care settings that dispense BRIXADI are specially certified under 505-1(f)(3)(B)

2. Implementation System
3. Timetable for Submission of Assessments

## **Appendix A: List of Professional Societies**

- AATOD – American Association of the Treatment of Opioid Dependence
- ASAM – American Society of Addiction Medicine
- AAAP - American Association of Addiction Psychiatry
- ABAM – American Board of Addiction Medicine
- FSMB – Federation of State Medical Boards
- ACEP – American College of Emergency Physicians
- NCPA – National Community of Pharmacists Association
- ASHP – American Society of Health-System Pharmacists
- AOAAM – American Osteopathic Academy of Addiction Medicine
- AANP – American Association of Nurse Practitioners
- AAPA – American Association of Physician Assistants
- Apha – American Pharmacists Association

## HEALTHCARE SETTING AND PHARMACY ENROLLMENT FORM

BRIXADI is only available through the BRIXADI Risk Evaluation and Mitigation Strategy (REMS).

### Instructions

If a healthcare setting or a pharmacy intends to store a supply of and order BRIXADI directly from an authorized distributor, certification in the BRIXADI REMS is required. To become certified, healthcare settings and pharmacies must:

1. Designate an Authorized Representative who can ensure the Authorized Representative responsibilities listed in the “Authorized Representative Information and Responsibilities” section of the enrollment form are met and that each dispensing location meets the REMS requirements.
2. 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.
  - Establish process and procedures to verify that BRIXADI is dispensed directly to a healthcare provider.  
**Do not dispense BRIXADI directly to a patient.**
  - Establish process and procedures to notify the healthcare provider not to dispense BRIXADI directly to patients.
3. Complete and sign this **BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form** and submit it to the BRIXADI REMS.

Once certification of the healthcare setting/pharmacy is complete, a notification will be provided to the Authorized Representative.

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

**Certification in the BRIXADI REMS is not required if a healthcare setting intends to only obtain BRIXADI for administration by a practitioner at a specific named patient’s scheduled appointment from a REMS-certified pharmacy.**

The **BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form** contains two sections:

- “Authorized Representative Information and Responsibilities” section – page 2
- “Healthcare Setting and Pharmacy Information” section – page 3

For the initial enrollment, both sections noted above must be submitted. For **each** additional healthcare setting/ pharmacy where BRIXADI will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative is responsible, the Authorized Representative will need to complete the “Healthcare Setting and Pharmacy Information” section on page 3.

If a designated Authorized Representative changes, the new Authorized Representative must complete and sign a new **BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form**, including a “Healthcare Setting Information” section for each healthcare setting with which he/she is now affiliated.

To enroll, complete all required fields on the form and one “Healthcare Setting / Pharmacy Information” section for each dispensing site and submit via:

- **Online:** [www.BRIXADIREMS.com](http://www.BRIXADIREMS.com)
- **FAX:** 1-833-274-8597
- **Email:** [BRIXADIREMS@braeburnrx.com](mailto:BRIXADIREMS@braeburnrx.com)
- **Mail:** BRIXADI REMS Program, 8517 Southpark Circle, Bldg. Suite 200, Orlando, FL 32819

For questions regarding the BRIXADI REMS or how to enroll, visit [www.BRIXADIREMS.com](http://www.BRIXADIREMS.com) or contact the BRIXADI REMS at 1-866-492-9624.

**HEALTHCARE SETTING AND PHARMACY ENROLLMENT FORM (cont'd)**

**Authorized Representative Information and Responsibilities**

**AUTHORIZED REPRESENTATIVE INFORMATION (\*REQUIRED FIELDS)**

**Role\***

- Nurse                       Nurse Practitioner                       Pharmacist                       Physician                       Physician Assistant  
 Practice Manager                       Other: \_\_\_\_\_

**Contact details\***

First name: \_\_\_\_\_ Last name: \_\_\_\_\_ Middle initial: \_\_\_\_\_  
 Position/Title: \_\_\_\_\_  
 Telephone number: \_\_\_\_\_ Alternate telephone number: \_\_\_\_\_ Office fax: \_\_\_\_\_  
 Email: \_\_\_\_\_ Preferred method of communication:  Fax  Email  Phone

I am the Authorized Representative designated to carry out the certification process and oversee implementation and compliance with the REMS on behalf of my healthcare setting or pharmacy. By signing this form, I agree to:

- Certify in the BRIXADI REMS by completing the Healthcare Setting and Pharmacy Enrollment Form and submitting it to the REMS.
- 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 that BRIXADI must not be dispensed directly to a patient.
- Establish processes and procedures to verify BRIXADI is dispensed directly to a healthcare provider, and BRIXADI is not dispensed 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.
- Not distribute, transfer, loan, or sell BRIXADI.
- Maintain records of all processes and procedures including compliance with those processes and procedures.
- Comply with audits by Braeburn or a third party acting on behalf of Braeburn to ensure that all processes and procedures are in place and being followed for the BRIXADI REMS.

By checking this box, you understand that your healthcare setting/pharmacy may be selected for audit within 90 days.

Healthcare Setting or Pharmacy Authorized Representative Signature\*: \_\_\_\_\_

Date\* (MM/DD/YYYY): \_\_\_ / \_\_\_ / \_\_\_\_

**By signing I acknowledge that I understand that there is a risk of serious harm or death that could result from intravenous self-administration of BRIXADI, and to not dispense BRIXADI directly to a patient. I understand that this enrollment applies to my healthcare setting(s) or pharmacy(ies) for which I am the designated Authorized Representative.**

## HEALTHCARE SETTING AND PHARMACY ENROLLMENT FORM (cont'd)

### Healthcare Setting and Pharmacy Information

Healthcare Setting/Pharmacy Name: \_\_\_\_\_

Street Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_

Facility Identifiers (DEA registration mandatory) DEA: \_\_\_\_\_ NPI: \_\_\_\_\_ NCPDP: \_\_\_\_\_

Authorized Representative Name: \_\_\_\_\_

Primary Point of Contact IF NOT the Authorized Representative: \_\_\_\_\_

Point of Contact Name: \_\_\_\_\_

Street Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP: \_\_\_\_\_

Telephone Number: \_\_\_\_\_ Alternate Telephone Number: \_\_\_\_\_ Office Fax: \_\_\_\_\_

Email: \_\_\_\_\_ Preferred Method of Communication:  Fax  Email  Phone

### Setting Type

**Pharmacy**

Specialty  Other: \_\_\_\_\_

**Healthcare Setting**

Closed Healthcare System  Criminal Justice Facility  Criminal Justice Facility Pharmacy

Department of Defense (DoD) Facility  Federally Qualified Health Center (FQHC)  FQHC Pharmacy

Group Practice  Hospital  Hospital Pharmacy  Independent Practice

Institution  Institution Pharmacy  Integrated Delivery Network (IDN)

IDN Pharmacy  Opioid Treatment Program (OTP)  Outpatient Clinic

Veterans Administration (VA) Facility  VA Pharmacy

Other: \_\_\_\_\_

I am the designated Authorized Representative for this healthcare setting or pharmacy.

Healthcare Setting or Pharmacy Authorized Representative Signature: \_\_\_\_\_

Date (MM/DD/YYYY): \_\_\_ / \_\_\_ / \_\_\_\_



BRIXADI (buprenorphine) extended-release injection for subcutaneous use CIII

**FDA-REQUIRED REMS SAFETY INFORMATION**

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

- **Serious harm or death could result if administered intravenously. BRIXADI forms a liquid crystalline gel 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, BRIXADI is only available through a restricted program called the BRIXADI REMS. Healthcare settings and pharmacies that order and dispense BRIXADI 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 **BRIXADI Risk Evaluation and Mitigation Strategy (REMS)**. The FDA determined that a **REMS** is necessary to ensure that the benefits of BRIXADI outweigh the **risk of serious harm or death that could result from intravenous self-administration of BRIXADI**.

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

**BRIXADI REMS Requirements:**

- Any pharmacy or healthcare setting (including a prescriber office) that intends to store a supply of and order BRIXADI directly from an authorized distributor **must be certified** in the BRIXADI REMS prior to purchasing/dispensing BRIXADI.

**NOTE:** Certification in the BRIXADI REMS is **not required** if a healthcare setting intends to only obtain BRIXADI 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 BRIXADI.
- **BRIXADI must never be dispensed directly to a patient.**

The enclosed ***BRIXADI REMS Fact Sheet: How to Obtain BRIXADI*** provides information about **how your healthcare setting or pharmacy can obtain BRIXADI**.

Please visit [www.BRIXADIREMS.com](http://www.BRIXADIREMS.com) or contact the BRIXADI REMS at 1-866-492-9624 for BRIXADI REMS materials and for information about **how your healthcare setting or pharmacy can certify** in the BRIXADI REMS. For medical-related questions, call Braeburn's Information line at 1-833-274-9234.

## Indication

BRIXADI 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.

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

## BRIXADI Storage

Store BRIXADI at room temperature at 20°C to 25°C (68°F to 77°F); with excursions permitted at 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. BRIXADI is a Schedule III drug product. Handle with adequate security and accountability. After administration, syringes should be properly disposed, per facility procedure for a Schedule III drug product, and per applicable federal, state, and local regulations.

## 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 BRIXADI to the FDA at 1-800-FDA-1088 or online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) or to Braeburn at 1-833-274-9234 or send information to [drugsafety@braeburnrx.com](mailto:drugsafety@braeburnrx.com).

Sincerely,

<NAME>

<TITLE> Braeburn

**The BRIXADI REMS Fact Sheet is enclosed. You can also access it by visiting [www.BrixadiRems.com/Fact-Sheet](http://www.BrixadiRems.com/Fact-Sheet) or scanning the QR code below:**



### What is the BRIXADI REMS (Risk Evaluation and Mitigation Strategy)?

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. **BRIXADI is intended for subcutaneous injection only by a healthcare provider** and is only available through a restricted distribution program called the BRIXADI REMS. **BRIXADI must never be dispensed directly to the patient and must only be administered by a healthcare professional** in a healthcare setting. The goal of the REMS is to mitigate **the risk of serious harm or death that could result from intravenous self-administration.**

### BRIXADI REMS Requirements

#### PRESCRIBER

1. Prescribers are **NOT required to be certified** in the BRIXADI REMS to prescribe BRIXADI.
2. Prescribers can obtain BRIXADI for a specific named patient's scheduled appointment by writing a prescription and sending it to a REMS-certified pharmacy. The REMS-certified pharmacy coordinates delivery to the prescriber or the practitioner administering BRIXADI with the patient's appointment date.
3. Prescribers that intend to keep a supply of BRIXADI in stock at their healthcare setting and obtain BRIXADI from a distributor, **must certify** their healthcare setting or practice in the BRIXADI REMS. See below.

#### HEALTHCARE SETTINGS/PHARMACIES

Any healthcare setting\* (including a prescriber office) or pharmacy that intends to keep a supply of BRIXADI in stock and order BRIXADI directly from an authorized distributor **must be certified** in the BRIXADI REMS prior to purchasing/dispensing BRIXADI.

\*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, and other healthcare settings.

### How does a healthcare setting\* or pharmacy become certified?

#### To become certified in the BRIXADI REMS, healthcare settings and pharmacies must:

1. Designate an Authorized Representative that agrees to:
  - Train all relevant staff at each dispensing location involved in the dispensing of BRIXADI directly to a healthcare provider, to ensure that the drug is not dispensed directly to a patient.
  - Establish processes and procedures to verify that BRIXADI is dispensed directly to a healthcare provider. **BRIXADI must never be dispensed directly to a patient.**
  - Establish processes and procedures to notify the healthcare provider not to dispense BRIXADI directly to patients.
2. Complete the REMS enrollment process by filling out and signing the Healthcare Setting and Pharmacy Enrollment Form, which may be obtained at [www.BRIXADIREMS.com](http://www.BRIXADIREMS.com)

***BRIXADI must never be dispensed directly to a patient.***

**Does a prescriber that wants to have BRIXADI administered to a named patient at their scheduled appointment need to certify? How can healthcare providers obtain BRIXADI for their patients?**

Prescribers do not need to certify in the REMS. In advance of the patient's appointment, send a prescription for the named patient to a certified pharmacy. REMS-certified pharmacies can be found on the REMS website ([www.BRIXADIREMS.com](http://www.BRIXADIREMS.com)) or by calling 1-866-492-9624. The pharmacy will coordinate delivery with the patient's scheduled appointment and deliver to the prescriber or the administering practitioner designated by the prescriber.

**BRIXADI is never dispensed directly to the patient and must only be administered by a healthcare professional in a healthcare setting.**

**Does a prescriber that wants to keep a bulk supply of BRIXADI in stock at their office need to certify? How does a prescriber obtain BRIXADI?**

The prescriber's office/healthcare setting must certify in the REMS and obtain BRIXADI through an authorized distributor.

**How should BRIXADI be stored?**

Once BRIXADI is delivered for a named patient or is obtained for a healthcare setting's bulk supply:

- Store BRIXADI at room temperature at 20°C to 25°C (68°F to 77°F); with excursions permitted at 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
- BRIXADI is a Schedule III drug product. Handle with adequate security and accountability. After administration, syringes should be properly disposed per facility procedure for a Schedule III drug product and per applicable federal, state, and local regulations.

**Where can I find more information about the BRIXADI REMS?**

Visit [www.BRIXADIREMS.com](http://www.BRIXADIREMS.com) to access the following materials:

- **BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form**
- **BRIXADI REMS Dear Healthcare Provider Letter**
- **Prescribing Information**
- **Medication Guide**
- **REMS-Certified Pharmacy Locator**
- **List of Authorized Distributors**

Contact the BRIXADI REMS at 1-866-492-9624 for BRIXADI REMS materials and for additional information about the BRIXADI REMS.

Visit the REMS@FDA website at <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>.

**Call Braeburn's information line at 1-833-274-9234.**



## Welcome to the BRIXADI REMS (Risk Evaluation and Mitigation Strategy)

### What is the BRIXADI REMS (Risk Evaluation and Mitigation Strategy)?

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. **BRIXADI is intended for subcutaneous injection only by a healthcare provider** and is only available through a restricted distribution program called the BRIXADI REMS. BRIXADI must never be dispensed directly to the patient and must only be administered by a healthcare professional in a healthcare setting. The goal of the REMS is to mitigate the risk of serious harm or death that could result from intravenous self-administration.

### BRIXADI REMS Requirements

#### PRESCRIBERS

1. Prescribers are **NOT required to be certified** in the BRIXADI REMS to prescribe BRIXADI.
2. Prescribers can obtain BRIXADI for a specific named patient's scheduled appointment by writing a prescription and sending it to a REMS-certified pharmacy. The REMS-certified pharmacy coordinates delivery to the prescriber or the practitioner administering BRIXADI with the patient's appointment date.
3. Prescribers that intend to keep a supply of BRIXADI in stock at their healthcare setting and obtain BRIXADI from a distributor, **must certify** their healthcare setting or practice in the BRIXADI REMS. See below.

#### HEALTHCARE SETTINGS\*/PHARMACIES

Any healthcare setting\* (including a prescriber office) or pharmacy that intends to keep a supply of BRIXADI in stock and order BRIXADI directly from an authorized distributor **must be certified** in the BRIXADI REMS prior to purchasing/dispensing BRIXADI.

\* 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, and other healthcare settings.

### How does a healthcare setting or pharmacy become certified in the BRIXADI REMS?

To become certified in the BRIXADI REMS, healthcare settings and pharmacies must:

#### 1. Designate an Authorized Representative that agrees to:

- Train all relevant staff at each dispensing location involved in the dispensing of BRIXADI directly to a healthcare provider, to ensure that the drug is not dispensed directly to a patient.
- Establish processes and procedures to verify that BRIXADI is dispensed directly to a healthcare provider. **BRIXADI must never be dispensed directly to a patient.**
- Establish processes and procedures to notify the healthcare provider not to dispense BRIXADI directly to patients.

#### 2. Complete the REMS enrollment process by filling out and signing the [Healthcare Setting and Pharmacy Enrollment Form](#)

### Does a prescriber that wants to have BRIXADI administered to a named patient at their scheduled appointment need to certify? How can healthcare providers obtain BRIXADI for their patients?

Prescribers do not need to certify in the REMS. In advance of the patient's appointment, send a prescription for the named patient to a certified pharmacy. REMS-certified pharmacies can be found [here](#) or by calling 1-866-492-9624. The pharmacy will coordinate delivery with the patient's scheduled appointment and deliver to the prescriber or the administering practitioner designated by the prescriber. **BRIXADI is never dispensed directly to the patient and must only be administered by a healthcare professional in a healthcare setting.**

### Does a prescriber that wants to keep a bulk supply of BRIXADI in stock at their office need to certify? How does a prescriber obtain BRIXADI?

The prescriber's office/healthcare setting must certify in the REMS and obtain BRIXADI through an authorized distributor.

### How should BRIXADI be stored?

Once BRIXADI is delivered for a named patient or is obtained for a healthcare setting's bulk supply:

- Store BRIXADI at room temperature at 20°C to 25°C (68°F to 77°F); with excursions permitted at 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
- BRIXADI is a Schedule III drug product. Handle with adequate security and accountability. After administration, syringes should be properly disposed per facility procedure for a Schedule III drug product and per applicable federal, state, and local regulations.

### Where can healthcare settings and pharmacies find more information about the BRIXADI REMS?

- Review the following materials:
  - [BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form](#)
  - [BRIXADI REMS Fact Sheet: How to Obtain BRIXADI](#)
  - [BRIXADI REMS Dear Healthcare Provider Letter](#)
  - [Prescribing Information](#)
  - [Medication Guide](#) (educational tool designed specifically for patients)
- Contact the BRIXADI REMS at 1-866-492-9624 for REMS materials and for additional information about the BRIXADI REMS.
- Visit the REMS@FDA website at: <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>.
- Call Braeburn's Information line (1-833-274-9234).

To access the current list of certified pharmacies where you can obtain BRIXADI, you can call BRIXADI REMS at 1-866-492-9624 or click [here](#).

#### Indication

BRIXADI 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.

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

#### 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 BRIXADI to the FDA at 1-800-FDA-1088 or online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) or to Braeburn at 1-833-274-9234 or send information to [drugsafety@braeburnrx.com](mailto:drugsafety@braeburnrx.com).

#### Resources for Healthcare Providers

- [BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form](#)
- [BRIXADI REMS Fact Sheets](#)
- [Dear Healthcare Provider Letter](#)

CERTIFICATION PORTAL

**BRIXADI must never be dispensed directly to a patient.**

MANAGE CONSENT

[Contact Us](#)

[Privacy Policy](#)

[Terms of Use](#)

[Medication Guide](#)

[Prescribing Information](#)

BRIXADI is a registered trademark of Braeburn, Inc.  
This site is intended for US residents only.  
© 2023 Braeburn, Inc. All rights reserved.

 braeburn

## BRIXADI REMS Online Enrollment Form

Please enter your information to receive an email notification from BRIXADI REMS with instructions to complete the BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form.

SUBMIT

[Contact Us](#)

[Privacy Policy](#)

[Terms of Use](#)

[Medication Guide](#)

[Prescribing Information](#)

BRIXADI is a registered trademark of Braeburn, Inc.  
This site is intended for US residents only.  
2023 Braeburn, Inc. All rights reserved.



Thank you for your submission. In moments you will be receiving an email notification from BRIXADI REMS with instructions to complete the BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form. If you do not receive this email, please call 1-866-492-9624.

#### Resources for Healthcare Providers

- [BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form](#)
- [BRIXADI REMS Fact Sheet](#)
- [Dear Healthcare Provider Letter](#)

CERTIFICATION PORTAL

**BRIXADI must never be dispensed directly to a patient.**

[Contact Us](#)

[Privacy Policy](#)

[Terms of Use](#)

[Medication Guide](#)

[Prescribing Information](#)

BRIXADI is a registered trademark of Braeburn, Inc.  
This site is intended for US residents only.  
2023 Braeburn, Inc. All rights reserved.



Email Notification:



**Complete the requested form from Braeburn.**

Braeburn has requested you to review and complete the BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form

Get Started

**[Get started now](#)**

Braeburn is using Dropbox Forms to give you the best mobile signing experience. [Try Dropbox Forms for free.](#)

---

 Warning: To prevent others from accessing your account, do not forward this email.

## Get Started Page:



---

### **BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form**

Click 'Get Started' below to begin.

---

**Authorized Representative Information and  
Responsibilities**

---

**Healthcare Setting and Pharmacy Enrollment  
Form**

---

**Get started**



## Authorized Representative Information and Responsibilities

---

BRIXADI is only available through the BRIXADI Risk Evaluation and Mitigation Strategy (REMS).

If a healthcare setting or a pharmacy intends to store a supply of and order BRIXADI directly from an authorized distributor, certification in the BRIXADI REMS is required. To become certified, healthcare settings and pharmacies must:

1. Designate an Authorized Representative who can ensure the Authorized Representative responsibilities listed in the “Authorized Representative Information and Responsibilities” section of the enrollment form are met and that each dispensing location meets the REMS requirements.
2. 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.
  - Establish process and procedures to verify that BRIXADI is dispensed directly to a healthcare provider. **Do not dispense BRIXADI directly to a patient.**
  - Establish process and procedures to notify the healthcare provider not to dispense BRIXADI directly to patients.

---

3. Complete and sign this ***BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form*** and submit it to the BRIXADI REMS.

Once certification of the healthcare setting/pharmacy is complete, a notification will be provided to the Authorized Representative.

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

***Certification in the BRIXADI REMS is not required if a healthcare setting intends to only obtain BRIXADI for administration by a practitioner at a specific named patient's scheduled appointment from a REMS-certified pharmacy.***

The ***BRIXADI REMS Healthcare Setting and Pharmacy Enrollment Form*** contains two sections:

- "Authorized Representative Information and Responsibilities" section
- "Healthcare Setting and Pharmacy Information" section

For the initial enrollment, both sections noted above must be submitted. For **each** additional healthcare setting/ pharmacy where BRIXADI will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative is responsible, the Authorized Representative will need to complete the "Healthcare Setting and Pharmacy Information" section.

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

This is the online enrollment form. Please complete all required fields in the pages to follow.

For questions regarding the BRIXADI REMS or how to enroll, visit [www.BRIXADIREMS.com](http://www.BRIXADIREMS.com) or contact the BRIXADI REMS at 1-866-492-9624.

I acknowledge that I have read the instructions  
(uncheck to review again)

**Request Type \***

- New REMS Request
- Update an Existing REMS

**Role \***

Select an item... ▼

**First Name \***

**Middle Initial**

**Last Name \***

**Position/Title \***

**Telephone Number \***

**Alternative Telephone Number**

**Office Fax Number****Email \*****Preferred Method of Communication \*** 

I am the Authorized Representative designated to carry out the certification process and oversee implementation and compliance with the REMS on behalf of my healthcare setting or pharmacy. By signing this form, I agree to:

- Certify in the BRIXADI REMS by completing the Healthcare Setting and Pharmacy Enrollment Form and submitting it to the REMS.
- 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 that BRIXADI must not be dispensed directly to a patient.
- Establish processes and procedures to verify BRIXADI is dispensed directly to a healthcare provider, and BRIXADI is not dispensed 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.
- Not to distribute, transfer, loan, or sell BRIXADI.
- Maintain records of all processes and procedures including compliance with those processes and procedures.

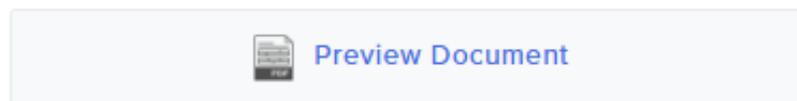
- Comply with audits by Braeburn or a third party acting on behalf of Braeburn to ensure that all processes and procedures are in place and being followed for the BRIXADI REMS.

**By signing I acknowledge that I understand that there is a risk of serious harm or death that could result from intravenous self-administration of BRIXADI, and to not dispense BRIXADI directly to a patient. I understand that this enrollment applies to my healthcare setting(s) or pharmacy(ies) for which I am the designated Authorized Representative.**

- \* By checking this box, you understand that your healthcare setting/pharmacy may be selected for audit within 90 days.



**Signature Date:** 03/21/2025



## Authorized Representative Dynamic Form Details:

Request Type Update:

### Request Type \*

- New REMS Request  
 Update an Existing REMS

### Existing REMS ID to Replace \* ?

Role Types:

### Role \*

Select an item... ▼

Select an item...

- Pharmacist
- Physician Assistant
- Practice Manager
- Nurse
- Nurse Practitioner
- Physician
- Other

Role Type "Other" Selection:

### Role \*

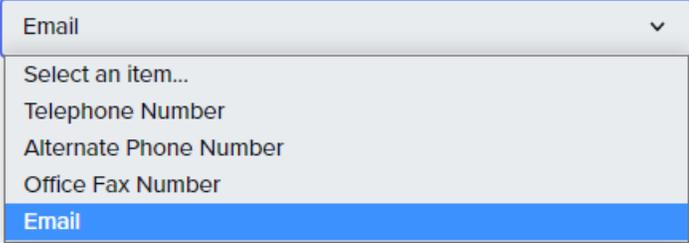
Other ▼

### If Other, Please Specify: \*

### First Name \*

Preferred Communication Method Options:

**Preferred Method of Communication \***



A dropdown menu with a light gray background and a blue border. The top bar is labeled "Email" on the left and has a downward-pointing chevron icon on the right. The menu is open, showing a list of options: "Select an item...", "Telephone Number", "Alternate Phone Number", "Office Fax Number", and "Email". The "Email" option at the bottom is highlighted with a blue background.

Email	▼
Select an item...	
Telephone Number	
Alternate Phone Number	
Office Fax Number	
Email	

Program Requirements Agreement selection:

---

I am the Authorized Representative designated to carry out the certification process and oversee implementation and compliance with the REMS on behalf of my healthcare setting or pharmacy. By signing this form, I agree to:

- Certify in the BRIXADI REMS by completing the Healthcare Setting and Pharmacy Enrollment Form and submitting it to the REMS.
- 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 that BRIXADI must not be dispensed directly to a patient.
- Establish processes and procedures to verify BRIXADI is dispensed directly to a healthcare provider, and BRIXADI is not dispensed 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.
- Not to distribute, transfer, loan, or sell BRIXADI.
- Maintain records of all processes and procedures including compliance with those processes and procedures.
- Comply with audits by Braeburn or a third party acting on behalf of Braeburn to ensure that all processes and procedures are in place and being followed for the BRIXADI REMS.

**By signing I acknowledge that I understand that there is a risk of serious harm or death that could result from intravenous self-administration of BRIXADI, and to not dispense BRIXADI directly to a patient. I understand that this enrollment applies to my healthcare setting(s) or pharmacy(ies) for which I am the designated Authorized Representative.**

\* By checking this box, you understand that your healthcare setting/pharmacy may be selected for audit within 90 days.

You must review the terms and conditions before you can submit the REMS request.

## Healthcare Setting Flat Form:



Document 2 of 2

# Healthcare Setting and Pharmacy Enrollment Form

---

I acknowledge that I have read the instructions  
(uncheck to review again)

### Request Type \*

- New REMS Request
- Update an Existing REMS

Click the Authorized Representative signature box below to confirm the application of this signature to your submission.

X CLICK TO SIGN

---

This field has an error

**Healthcare Setting Name \***

**Street Address \***

**City \***

**State \***

**Zipcode \***

**Facility Identifiers (DEA registration mandatory): \***

NPI

NCPDP

DEA \*

**Authorized Representative Name**

Jane G Smith

**Point of Contact Name**

**Street Address**

**City**

**State**

**Zipcode**

**Telephone Number**

**Alternative Telephone Number**

**Office Fax Number**

**Email**

### Preferred Method of Communication

Select an item... 

### Setting Type: \*

\* I am the designated Authorized Representative for this healthcare setting or pharmacy.



**Signature Date:** 03/21/2025

I have additional Healthcare Settings to submit for this Authorized Representative.

I agree to be legally bound by the document, and agree to the Dropbox Sign [Terms](#) and [Privacy Policy](#). Click on "I agree" to sign this document.

 [Preview Document](#)

## Healthcare Setting Dynamic Form Details:

### Facility Identifiers

**Facility Identifiers (DEA registration mandatory): \***

NPI

1234567890

NCPDP

1234567

DEA \*

AB1234567

DEA is required

### Preferred Method of Communication

**Preferred Method of Communication**

Select an item... ▼

- Select an item...
- Telephone Number
- Alternate Phone Number
- Office Fax Number
- Email

Setting Type Pharmacy Selection:

**Setting Type: \***

**Type of Pharmacy \***

Select an item...  
Select an item...  
Specialty  
Other

Setting Type Pharmacy Other Selection and Field:

**Setting Type: \***

**Type of Pharmacy \***

Other

Retail Pharmacy Submissions are not allowed. Any reference to retail in the other field will cause the REMS request to be rejected.

**If Other, Please Specify: \***

Retail entries will be rejected

Setting Type Healthcare Setting Selected:

**Setting Type: \***

Pharmacy

Healthcare Setting

**Type of Healthcare Setting \***

Select an item... ▼

- Select an item...
- Closed Healthcare System
- Criminal Justice Facility
- Criminal Justice Facility Pharmacy
- Department of Defense (DoD) Facility
- Federally Qualified Health Center (FQHC)
- FQHC Pharmacy
- Group Practice
- Hospital
- Hospital Pharmacy
- Independent Practice
- Institution
- Institution Pharmacy
- Integrated Delivery Network (IDN)
- IDN Pharmacy
- Opioid Treatment Program (OTP)
- Outpatient Clinic
- Veterans Administration (VA) Facility
- VA Pharmacy
- Other

Setting Type Healthcare Other Selection and Field:

**Setting Type: \***

Pharmacy	Healthcare Setting
----------	--------------------

**Type of Healthcare Setting \***

Other ▼

**If Other, Please Specify: \***

## Submitter Notification Verbiage:

Update of REMS Notification:

Data pulled in from system or form data.

Subject:

"REMS ID XXXXXXXX has been updated"

Body:

"Healthcare Setting Doe Treatment Center is now re-enrolled in the BRIXADI REMS Program with the REMS ID XXXXXXXX. The Authorized Representative for XXXXXXXX is John Doe. [Click Here](#) to download or print your signed document.

For BRIXADI REMS Program questions 1-866-492-9624.

An additional site request has been sent to [john.doe@test.com](mailto:john.doe@test.com)"

## New Enrollment Notification:

Subject:

"REMS ID XXXXXXXX has been completed"

Body:

"Healthcare Setting Doe Treatment Center is now enrolled in the BRIXADI REMS Program with the REMS ID XXXXXXXX. The Authorized Representative for XXXXXXXX is John Doe. [Click Here](#) to download or print your signed document.

For BRIXADI REMS Program questions please contact 1-866-492-9624.

An additional site request has been sent to [john.doe@test.com](mailto:john.doe@test.com)"

## Duplicate Enrollment Notification:

Subject:

"REMS ID XXXXXXXX has been updated"

Body:

"An Existing REMS Enrollment with REMS ID XXXXXXXX was identified. Due to the BRIXADI REMS reconciliation process your form has been updated. The REMS ID YYYYYYYY is no longer valid. Please review the updated form XXXXXXXX.

For BRIXADI REMS Program questions please contact 1-866-492-9624."