BRIXADI REMS

braeburn

Brixadi® (buprenorphine) extended-release injection for subcutaneous use (III)
Weekly 8 • 16 • 24 • 32 mg Monthly 64 • 96 • 128 mg

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
- **FAX:** 1-833-274-8597
- **Email:** 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 or contact the BRIXADI REMS at 1-866-492-9624.

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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.

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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**

☐ Contracted Alternate Injection Site ☐ 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 ☐ HCP Administration only (Alternate/Additional Site of Care (ASOC))

☐ 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): ___ /___ /_____