Brixadi®
(buprenorphine) extended-release
injection for subcutaneous use (CIII)

BRIXADI REMS FACT SHEET

How to Obtain BRIXADI

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

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) 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 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/rems/index.cfm.

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

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