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 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 or to Braeburn at 1-833-274-9234 or send information to drugsafety@braeburnrx.com.

Sincerely,

Paul Johnson

Chief Commercial Officer, Braeburn

The BRIXADI REMS Fact Sheet is enclosed, or you can also access it by visiting www.BrixadiRems.com/Fact-Sheet or scanning the QR code below: