

[BRAEBURN LOGO]

TRADENAME (buprenorphine extended-release) Injection for Subcutaneous Use CIII

FDA-REQUIRED REMS SAFETY INFORMATION

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

- **Serious harm or death could result if administered intravenously. TRADENAME forms a solid mass 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 administration, TRADENAME is only available through a restricted program called the TRADENAME REMS Program. Healthcare settings and pharmacies that order and dispense TRADENAME must be enrolled in this program and comply with the REMS requirements.**

[Date]

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 administration of TRADENAME**. The FDA has determined that a **Risk Evaluation and Mitigation Strategy (REMS)** is necessary to ensure that the benefits of TRADENAME outweigh this serious risk.

TRADENAME is available only through a restricted distribution program called the TRADENAME REMS Program because of **the risk of serious harm or death that could result from intravenous administration. TRADENAME is intended for subcutaneous injection only by a healthcare provider.**

What are the TRADENAME REMS Program Requirements?

- All healthcare settings and pharmacies that dispense TRADENAME must be enrolled in the TRADENAME REMS program.
- Healthcare providers, healthcare settings, and pharmacies must obtain TRADENAME through a restricted distribution program.
- **TRADENAME should never be dispensed directly to a patient.**

Prescriber offices that only order TRADENAME from an enrolled pharmacy for a specific patient are exempt from enrollment.

Please see the attached non-promotional *TRADENAME REMS Program Fact Sheet: How to Obtain TRADENAME*, reviewed by the FDA, for information about **how your healthcare setting or pharmacy can obtain TRADENAME**.

Please visit www.TRADENAMEREMS.com for information about **how your healthcare setting or pharmacy can enroll** in the TRADENAME REMS Program.

Where can I find more information about the TRADENAME REMS Program?

- Visit www.TRADENAMEREMS.com to access the following materials:
 - *TRADENAME REMS Program Healthcare Setting and Pharmacy Enrollment Form*
 - *TRADENAME REMS Program Fact Sheet: How to Obtain TRADENAME*
 - *Prescribing Information*
 - *Medication Guide* (educational tool designed specifically for patients)
- Contact the TRADENAME REMS Program at 1-XXX-XXX-XXXX for TRADENAME REMS materials and for additional information about the TRADENAME REMS Program.
- Visit the REMS@FDA website at:
<https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm>.
- Call Braeburn's Information line (1-XXX-XXX-XXXX).

Indication

TRADENAME is indicated for the the treatment of opioid use disorder and is preferred for treatment initiation.

TRADENAME 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 TRADENAME to the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm or to Braeburn at 1-XXX-XXX-XXXX or send information to xxx@Braeburn.com.

Sincerely,

<NAME>

<TITLE> Braeburn Inc.

Enclosed:

TRADENAME REMS Program Fact Sheet: How to Obtain TRADENAME

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

Store BRAND NAME at 20 to 25°C (68 to 77°); excursions permitted at 15 to 30° C (59 to 86° F) [see USP Controlled Room Temperature].

Store BRAND NAME in accordance with Federal and State controlled substance laws and regulations.