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What are the Key Differences between Brixadi® and Sublocade®?

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Introduction: Brixadi® and Sublocade® are buprenorphine (BPN) subcutaneous injections used in the treatment of opioid use disorder (OUD). Due to the risk of serious harm or death associated with inadvertent intravenous administration, both of these medications have various Risk Evaluation and Mitigation Strategy (REMS) requirements. A comparison of these BPN products is provided in this article.

Manufacturers:
- Brixadi®, Braeburn, Inc.
- Sublocade®, Indivior, Inc.

Food and Drug Administration (FDA) Approval Dates:
- Brixadi®, 5/23/2023
- Sublocade®, 11/30/2017

FDA-Approved Indications:
- **Brixadi®:** Treatment of moderate-to-severe OUD in patients who have initiated treatment with a single dose of transmucosal BPN product or who are already being treated with BPN.
- **Sublocade®:** Treatment of moderate-to-severe OUD in patients who have initiated treatment with a BPN-containing product, followed by dose adjustment for a minimum of 7 days.

Dosage Forms: Brixadi® is available as weekly and monthly formulations, whereas Sublocade® is only available as a monthly formulation.

Brixadi® single-dose, prefilled safety syringes available strengths:
Weekly: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, 32mg/0.64 mL
Monthly: 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL

Sublocade® single-dose, prefilled safety syringes available strengths:
Monthly: 100 mg/0.5 mL, 300 mg/1.5 mL

Dosage and Administration:
Brixadi®:
- May only be prepared and administered by health-care professionals (HCPs).

For BPN-naïve patients:
- Begin with a test dose of 4 mg transmucosal BPN to establish that BPN is tolerated without precipitating withdrawal and then transition to Brixadi® (weekly).
- The recommended weekly dose in patients not currently receiving BPN treatment is 24 mg of Brixadi® (weekly) titrated up over the first week of treatment.
- If needed, during this first week of treatment, administer an additional 8 mg dose of Brixadi® (weekly), waiting at least 24 hours after the previous injection, for a total weekly dose of 32 mg Brixadi® (weekly).
- Dosage adjustments can be made at weekly appointments, with the maximum Brixadi® (weekly) dose being 32 mg.

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For BPN-established patients:

- Patients currently being treated with a transmucosal BPN-containing product may be switched directly to either Brixadi® (weekly) or Brixadi® (monthly).

A summary of dosage conversions from transmucosal BPN to the weekly and monthly doses of Brixadi® is provided in Table 1.

Table 1: Sublingual BPN Dose Conversion to Brixadi®

Daily dose of SL BPN	Brixadi® (weekly)	Brixadi® (monthly)
≤ 6 mg	8 mg	--
8-10 mg	16 mg	64 mg
12-16 mg	24 mg	96 mg
18-24 mg	32 mg	128 mg

SL=Sublingual BPN=Buprenorphine

- Patients may be transitioned from weekly to monthly or from monthly to weekly dosing of Brixadi® based on clinical judgment.
- Brixadi® (weekly) should be administered in 7-day intervals. Brixadi® (monthly) should be administered in 28-day intervals.
- Doses of Brixadi® (weekly) CANNOT be combined to yield a monthly dose.
- Brixadi® should be injected slowly into the subcutaneous tissue of the buttock, thigh, abdomen, or upper arm.
- In patients who are not currently receiving BPN treatment, for Brixadi® (weekly), the upper arm site should only be used after steady-state has been achieved (after 4 consecutive doses).
- Brixadi® (weekly) should not be administered at the same site of injection for at least 8 weeks. No injection site rotation is required for Brixadi® (monthly).

Sublocade®:

- May only be prepared and administered by HCPs.

For BPN-naïve patients:

- Initiate Sublocade® treatment only following induction and dose adjustment with a transmucosal BPN-containing product delivering the equivalent of 8-24 mg/day of BPN for a minimum of 7 days.
- The recommended dose of Sublocade® following induction is 300 mg monthly for the first 2 months, followed by a maintenance dose of 100 mg monthly.

For BPN-established patients:

- Patients established on long-term treatment with transmucosal BPN (8-24 mg/day) and whose disease symptoms are controlled may be directly transitioned to Sublocade®.

A summary of dosage conversions from transmucosal BPN to Sublocade® injections #1 and #2 is provided in Table 2.

Table 2: Transmucosal BPN Conversion to Sublocade®

Transmucosal BPN Dose	Sublocade® Injection #1	Sublocade® Injection #2	Maintenance Dose
8–18 mg/day	300 mg	100 mg*	100 mg
20–24 mg/day	300 mg	300 mg	100 mg

*For patients still experiencing craving or withdrawal symptoms after the initial 300 mg dose, consider giving 300 mg as the second dose.
BPN=Buprenorphine

- Administer Sublocade® monthly with a minimum of 26 days between doses.
- Sublocade® should be injected slowly and steadily into the subcutaneous tissue of the abdomen.
- To avoid irritation, rotate injection sites and record the location of the injection to ensure that a different site is used at the time of the next injection.

Rate of Injection-Site Pain

- **Brixadi®: 9.9 %** (includes patients exposed to varying doses of both Brixadi® weekly and monthly formulations)
- **Sublocade®: 7.2%** (includes patients exposed to varying doses of Sublocade® monthly formulation)

Latex Content:

- **Brixadi®: YES**; the needle cap is synthetically derived from natural rubber latex
- **Sublocade®: NO**

Storage and Stability:

- **Brixadi®:** Store 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).
- **Sublocade®:** Store refrigerated at 2°C to 8°C (35.6°F to 46.4°F). Once outside the refrigerator this product may be stored in its original packaging at room temperature, 15°C to 30°C (59°F to 86°F), for up to 12 weeks before administration.

Formulary Status: Sublocade® and Brixadi® are restricted to Palliative Medicine and providers within Adult Behavioral Health for the treatment of OUD in adult patients and limited to outpatient use only.

References:

1. Brixadi® [package insert]. Cockeysville, MD: Braeburn Inc; December 2023.
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3. Email communication from Thomas Cargiulo. Senior Medical Science Liaison Field Medical Affairs for Indivior Inc. February 26, 2025.
4. Buprenorphine. *Lexi-Drugs*. UpToDate Lexidrug. UpToDate Inc. https://online.lexi.com. Accessed June 16, 2025.