Post-Launch Adverse Events Reported to FAERS for Long-Acting Injectable Buprenorphine

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BACKGROUND

- Two long-acting injectable buprenorphine (LAIB) medications are approved for the treatment of moderate to severe opioid use disorder (OUD): SUBLOCADE (BUP-SB, monthly) and BRIXADI (BUP-BX, weekly and monthly).[1,2]
- Randomized controlled trials have demonstrated the safety of LAIBs.[3,4] However, post-marketing data provide valuable insights into the safety of treatments within real-world populations.
- FDA Adverse Event Reporting System (FAERS) is a centralized public database used for post-marketing drug safety surveillance.[5]
- Adverse event (AE) rates from FAERS for BUP-SB and BUP-BX have not been previously analyzed.

METHODS

- This retrospective analysis evaluated AEs spontaneously reported to FAERS during the 12-month periods following US commercial launches of BUP-SB (March 1, 2018 to February 28, 2019) and BUP-BX (September 5, 2023 to September 4, 2024).
  - AEs reported in ≥5% of all case reports for each product were analyzed.
- AE reporting rates (RR) were calculated based on the total number of AEs per 1000 patients treated (RR_{pt}) and per 1000 units sold (RR_{rx}).
  - The total number of patients treated with/units sold of BUP-SB and BUP-BX during these periods was estimated based on publicly-reported figures and specialty pharmacy and distributor data.
- AE terms with an RR ≥1 for at least one of the products are reported.

RESULTS

- The estimated number of patients treated with BUP-SB and BUP-BX during these periods was 6,464 and 24,805, respectively, with an estimated 16,770 and 94,826 units sold.

Table 1. AE Reporting Rates in the First 12 Months Post-launch per 1000 Units Sold (RR_{rx}) and per 1000 Patients Treated (RR_{pt}) (RR ≥1 for either product)

AE Term	BUP-SB RR_{rx}	BUP-BX RR_{rx}	BUP-SB RR_{pt}	BUP-BX RR_{pt}
Withdrawal Syndrome	15.1 (13.4, 17.1)	1.1 (0.9, 1.3)	39.1 (34.7, 44.2)	4.2 (3.5, 5.1)
Injection Site Pain	15.0 (13.2, 16.9)	0.3 (0.2, 0.5)	38.8 (34.3, 43.8)	1.3 (0.9, 1.8)
Drug Dependence	3.5 (2.7, 4.5)	0.2 (0.2, 0.4)	9.0 (7.0, 11.6)	0.9 (0.6, 1.3)
Injection Site Erythema	3.0 (2.3, 4.0)	0.2 (0.1, 0.3)	7.9 (6.0, 10.4)	0.7 (0.4, 1.1)
Injection Site Discharge	3.0 (2.3, 3.9)	0.0 (0.0, 0.1)	7.7 (5.9, 10.2)	0.0 (0.0, 0.2)
Drug Abuse	2.6 (1.9, 3.5)	0.0 (0.0, 0.1)	6.7 (5.0, 9.0)	0.1 (0.0, 0.3)
Nausea	2.4 (1.8, 3.3)	0.2 (0.1, 0.3)	6.3 (4.7, 8.6)	0.6 (0.3, 1.0)
Therapeutic Response Shortened	0.7 (0.4, 1.3)	0.4 (0.3, 0.6)	1.9 (1.1, 3.2)	1.6 (1.2, 2.2)
Drug Ineffective	0.2 (0.1, 0.6)	0.4 (0.3, 0.5)	0.6 (0.2, 1.6)	1.4 (1.0, 2.0)

Figure 1. AE Reporting Rates in the First 12 Months Post-launch per 1000 Units Sold (RR ≥1 for either product)

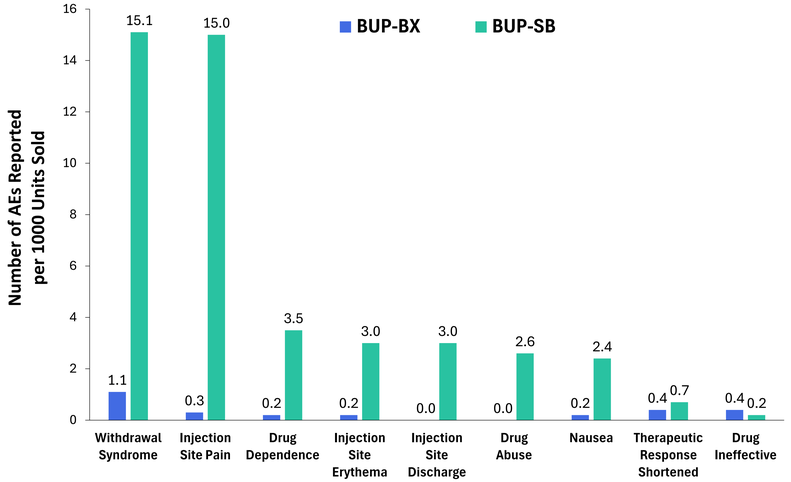
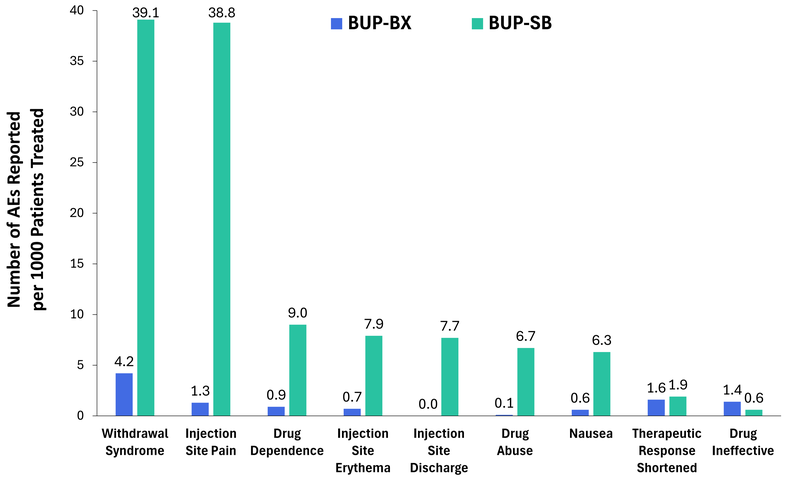


Figure 2. AE Reporting Rates in the First 12 Months Post-launch per 1000 Patients Treated (RR ≥1 for either product)



LIMITATIONS

- There is no certainty that reported AEs were caused by BUP-SB or BUP-BX, given the spontaneous and inconsistent manner in which cases are submitted to FAERS.[5]
- Some AEs related to these medications may not be reported.[5]
- These data may be impacted by the "Weber effect," which is the tendency for increased AE reporting during the initial period following a drug's approval.[6]
  - However, it has been suggested that the Weber effect is not generally observed for AE reporting to FAERS.[6]
- The total number of patients treated with/units sold of BUP-SB and BUP-BX in the 12-month periods following their US commercial launches was estimated using publicly-reported figures and specialty pharmacy and distributor data, which may be limited by incomplete data capture, duplication, and lack of direct linkage to drug administration.

CONCLUSIONS

- Overall, AEs reported for both BUP-SB and BUP-BX were infrequent during the 12-month periods following their US commercial launches.
- These data provide insights into the real-world safety profile of LAIB medications for the treatment of moderate to severe OUD and may help inform clinical decision-making.

REFERENCES

1. U.S Food & Drug Administration. FDA News Release. FDA approves first once-monthly buprenorphine injection, a medication-assisted treatment option for opioid use disorder. November 30, 2017. https://www.fda.gov/news-events/press-announcements/fda-approves-first-once-monthly-buprenorphine-injection-medication-assisted-treatment-option-opioid.
2. U.S Food & Drug Administration. FDA News Release. FDA Approves New Buprenorphine Treatment Option for Opioid Use Disorder. May 23, 2023. https://www.fda.gov/news-events/press-announcements/fda-approves-new-buprenorphine-treatment-option-opioid-use-disorder.
3. Haight BR, Learned SM, Laffont CM, et al. *Lancet*. 2019;393(10173):778-790.
4. Lofwall MR, Walsh SL, Nunes EV, et al. *JAMA Intern Med*. 2018;178(6):764–773.
5. US Food & Drug Administration. Questions and answers on FDA's Adverse Event Reporting System (FAERS). Accessed April 11, 2025. https://fis.fda.gov/extensions/FPD-FAQ/FPD-FAQ.html
6. Hoffman KB, Dimbil M, Erdman CB, et al. *Drug Saf*. 2014;37(4):283-294.

DISCLOSURES

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