Post-Launch Adverse Events Reported to FDA Adverse Event Reporting System for Long-Acting Injectable Buprenorphine

Brian J. Dawson[1], Michael P. Frost[2], **Natalie R. Budilovsky-Kelley**[3], Adam Friedman[3], Joshua M. Cohen[3]

[1]Ideal Option, Pasco, WA, USA; [2]The Frost Medical Group LLC, Conshohocken, PA, USA; [3]Braeburn Inc, Plymouth Meeting, PA, USA

BACKGROUND

- Two long-acting injectable buprenorphine (LAIB) medications are approved for the treatment of moderate to severe opioid use disorder (OUD): RBP-6000 (monthly) and CAM2038 (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 RBP-6000 and CAM2038 have not been previously analyzed.

METHODS

- This retrospective analysis evaluated AEs spontaneously reported to FAERS during the 12-month periods following the US commercial launches of RBP-6000 (March 1, 2018 to February 28, 2019) and CAM2038 (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 RBP-6000 and CAM2038 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 RBP-6000 and CAM2038 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	RBP-6000 RR_{rx}	CAM2038 RR_{rx}	RBP-6000 RR_{pt}	CAM2038 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)

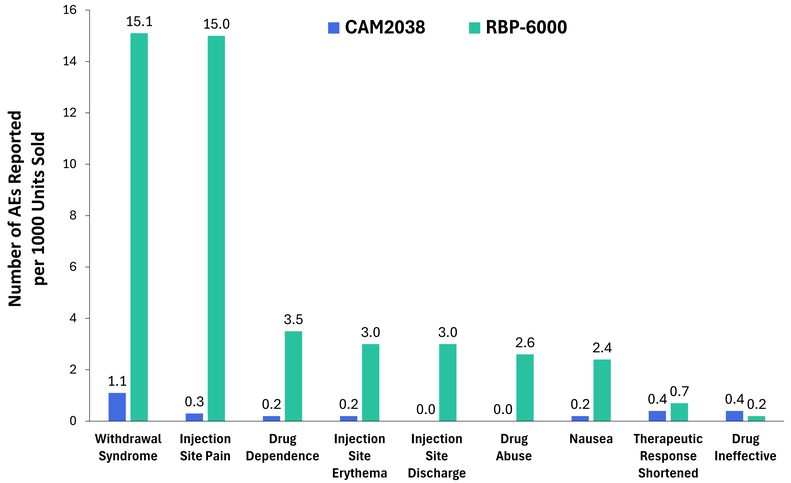
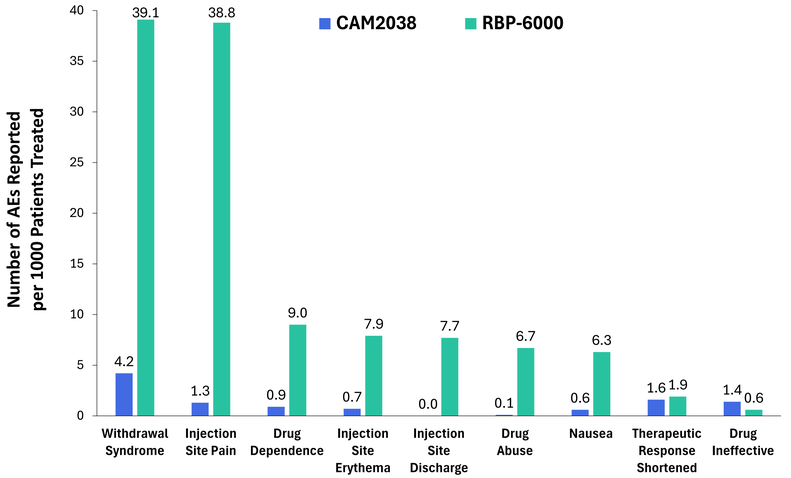


Figure 2. AE Reporting Rates in the First 12 Months Post-launch per 1000 Patients Treated (RR ≥1 for either product)



LIMITATIONS

- There is no certainty that reported AEs were caused by RBP-6000 or CAM2038, 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 RBP-6000 and CAM2038 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 RBP-6000 and CAM2038 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

BJD received speaking honoraria from Braeburn Inc. MPF received consulting/speaking honoraria from Braeburn Inc, received consultant fees from Molteni Farmaceutici and Accord Healthcare, and is a shareholder of Pocket Naloxone. NRB-K, AF, and JMC are current employees of Braeburn Inc.

Presented at the 2025 CSAM Annual Conference, Garden Grove, CA, August 13–16, 2025

MRC-1109 July 2025