

MONITORING SODIUM OXYBATE ABUSE THE REAL-WORLD: ACTIVE AND SPONTANEOUS SURVEILLANCE

Kate Reynolds^a, Joshua C. Black^a, Richard A. Olson^a, Jill D. Bowman^a, Richard C. Dart^a

^aRocky Mountain Poison and Drug Safety – Denver Health, Denver, CO

Phone: 303-881-3506

Email: jill.bowman@rmpds.org

BACKGROUND

- Sodium oxybate (gamma-hydroxybutyrate, GHB) is FDA approved to treat sleep disorders
- Trade names for sodium oxybate are Xyrem[®], Xywav[®], Lumryz[®]
- Prescription forms are under a Risk Evaluation and Mitigation Strategy (REMS) because the illicit form is abused recreationally
- Monitoring abuse is important to understanding the real-world safety of oxybate and whether the REMS are effective in preventing serious risk

RESULTS

NMURx

- A small (nonzero) prevalence of use was observed, which was consistent across 3 years of surveillance (Table 2)

NPDS

- 3,871 cases were identified involving the oxybate generic code
- Cases peaked in 2020 and then decreased afterward (Table 3)
- Cases classified as intentional abuse decreased after a peak in 2020 (Table 3)
- No cases were reported through the RADARS System Drug Diversion program
- One submission for information about sodium oxybate pricing was recorded on StreetRx in 2022-2023

CONCLUSIONS

- Prescription and illicit forms of sodium oxybate are used both non-medically and abused
- The prevalence of endorsements of prescription oxybate use is low, but above zero
- The number of poison center cases for abuse appeared to increase then decrease between 2018-2023; there were no reports of diversion, and only one street sale of prescription oxybate
- With potential increasing misuse of illicit forms of sodium oxybate, the possibility for abuse of the FDA approved form is possible
- The relationship between licit and illicit forms of sodium oxybate requires further research using active surveillance systems and spontaneous reports to monitor the real-world risk of these drugs, particularly as use of the prescription form increases

METHODS

Two surveillance systems were searched for data on sodium oxybate (Table 1)

- RADARS[®] System is a surveillance system that collects real-world safety and effectiveness data about prescription drugs thorough a mosaic of six data collection programs
- America's Poison Centers[®] (APC) maintains the National Poison Data System[®] (NPDS), which houses de-identified records of self-reported information from callers to the country's Poison Centers (PCs)

Table 1: Surveillance Sources

| RADARS [®] System (Researched Abuse, Misuse and Addiction-Related Surveillance) | | | |
|--|---|--------------|---|
| Program | Description | Search Dates | Search Terms |
| NMURx (Non-Medical Use ^b of Prescription Drugs) | A nationally representative online survey that collects data on non-medical use of drugs from 30,000 respondents biannually | 2021-2023 | prescription sodium oxybate |
| DD (Drug Diversion Program) | Cases of diversion reported by law enforcement agencies | 2022 - 2023 | sodium oxybate |
| StreetRx | A website that crowdsources street prices for diverted or illicit drugs | 2022 - 2023 | sodium oxybate |
| America's Poison Centers | | | |
| NPDS (National Poison Data System) | De-identified records of self-reported information from callers to the U.S. Poison Centers (PCs) | 2018 - 2023 | oxybate generic code (includes both illicit and prescription) |

^bNon-medical use (NMU) is defined as use in a way not directed by your healthcare provider

Table 2: NMURx Past 12 Month NMU^b by Surveillance Year

| | 2021 % (95% CI) | 2022 % (95% CI) | 2023 % (95% CI) |
|---|----------------------|----------------------|----------------------|
| NMU of Prescription oxybate, prevalence | 0.16 (0.13, 0.19) | 0.14 (0.10, 0.17) | 0.17 (0.12, 0.21) |

Table 3: NPDS Cases by Year

| | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 |
|-------------------------|------|------|------|------|------|------|
| All NPDS cases | 617 | 730 | 766 | 637 | 558 | 563 |
| Intentional abuse cases | 280 | 301 | 318 | 255 | 217 | 181 |

LIMITATIONS

- NPDS and StreetRx data depend on spontaneous reporting, which may result in underreporting of exposures
- NMURx limitations are recall and non-response biases, which are inherent in survey panels
- DD is not nationally representative as law enforcement agencies opt-in to participation