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Individualized Dosing and Drug Utilization of Low-Sodium Oxybate in Narcolepsy and Idiopathic Hypersomnia: Results From Post-Marketing Data

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Objective

- To describe real-world utilization of stable LXB dosing regimens and individualized LXB dosing patterns for individuals in the Risk Evaluation and Mitigation Strategy (REMS) with narcolepsy or idiopathic hypersomnia

Conclusions

- Formulation as an oral solution enables LXB to be prescribed in tailored, individualized dosing regimens, allowing for unique once- or twice-nightly dosing regimens; in this analysis, regimens with LXB split into 3 or more nightly doses were possible given the unique profile of the medication
- Our analysis showed that while >90% of prescribed LXB regimens were as indicated in the prescribing information and encompassed over 150 distinct regimens, a notable variety of other dosing regimens was feasible for use when clinically warranted to optimize effectiveness and tolerability
- These prescription data extracted from the REMS demonstrate the wide range of dosing regimens utilized in real-world prescribing to address patient needs and provide individualized, patient-centered care with LXB

References: 1. Morse AM, et al. *Neurol Ther.* 2024;13(3):785-807. **2.** Schneider LD, et al. *Nat Sci Sleep.* 2023;15:663-675. **3.** Arnulf I, et al. *Sleep Med Rev.* 2023;69:101766. **4.** Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution, CIII [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

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Disclosures: N Gavrielov-Yusim, J Dai, P Balmuri, A Saumweber, D Singer, V Patodiya, and **S Markt** are full-time employees and **F Skobieranda** is a former employee of Jazz Pharmaceuticals; in the course of this employment, these individuals have received stock options exercisable for, and other stock awards of, ordinary shares of Jazz Pharmaceuticals, plc. **J Nelms** is a contract worker for Jazz Pharmaceuticals.

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Introduction

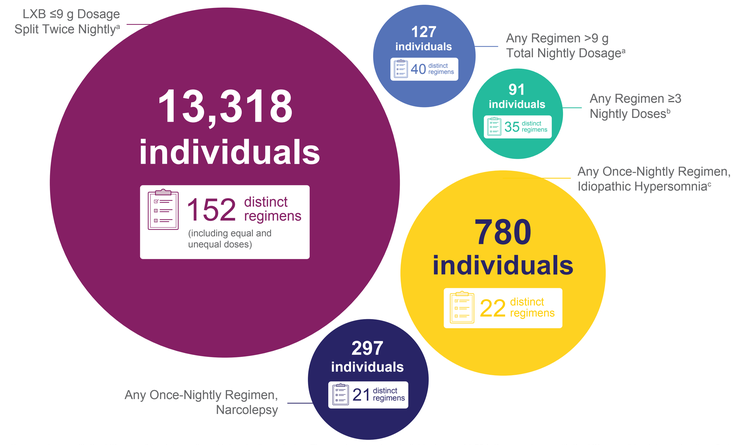
- The importance of using individualized low-sodium oxybate (LXB) dosing regimens to balance effectiveness and tolerability and to address the lifestyle needs of individuals with narcolepsy or idiopathic hypersomnia is supported by consensus recommendations and expert opinion[1-3]
  - LXB doses and/or dosing regimens may be adjusted for reasons including: addressing sleep initiation and/or maintenance, avoiding adverse effects, use of concomitant medications, and presence of comorbidities[1-3]
- Low-sodium oxybate (LXB, Xywav®) is an oral solution approved by the United States (US) Food and Drug Administration (FDA) for the treatment of excessive daytime sleepiness and cataplexy in individuals 7 years of age and older with narcolepsy and for the treatment of idiopathic hypersomnia in adults [4]
  - For adults with narcolepsy, LXB is initiated at 4.5 g per night orally, divided into 2 doses; the recommended dosage range is 6 g to 9 g per night, divided equally or unequally into 2 doses[4]
  - For adults with idiopathic hypersomnia, LXB can be taken as a twice- or once-nightly regimen. For twice-nightly regimens, LXB is initiated at ≤4.5 g per night, divided into 2 doses, up to 9 g total nightly dose. For once-nightly regimens, LXB is initiated at ≤3 g per night as one dose, up to 6 g total nightly dose[4]
- In the US, all individuals prescribed oxybate medications must be enrolled in the Risk Evaluation and Mitigation Strategy (REMS) (ie, XYWAV and XYREM REMS), the goal of which is to mitigate the risks of serious adverse outcomes resulting from inappropriate prescribing, misuse, abuse, and diversion by educating prescribers, pharmacists, and patients and by ensuring the pharmacy has controls in place prior to filling prescriptions[4]
  - All prescribers must order the prescription for LXB using a prescription form and submit it to the certified pharmacy via the XYWAV and XYREM REMS

Methods

- This retrospective descriptive analysis was conducted to characterize LXB dosing regimens prescribed in real-world clinical practice among adults (aged ≥18 years) enrolled in the REMS from January 1, 2019, to April 30, 2024
- Data are reported for individuals with narcolepsy or idiopathic hypersomnia who were prescribed and maintained a stable LXB dosing regimen, defined as >90 days of exposure to a given LXB dosing regimen (ie, no changes in dosing regimen for >90 days)
  - In this analysis, this period was considered the minimal length of maintenance treatment (as opposed to titration to an optimal dose) in the course of disease management
- Individuals were assigned to dosing regimen cohorts by indication (narcolepsy or idiopathic hypersomnia)
  - Cohorts were defined as 5 arrays of stable LXB dosing regimens
  - Stable LXB dosing regimens were grouped into the following 5 dosing regimen cohorts: ≤9 g twice-nightly, >9 g total nightly dosage, any regimen ≥3 nightly doses, once-nightly idiopathic hypersomnia, once-nightly narcolepsy
  - Individuals could have taken more than one stable LXB dosing regimen during the study period, and therefore could have been counted in multiple dosing regimen cohorts
- Prescribed LXB dosing regimens were summarized descriptively

Results

Figure 1. Number of Individuals and Dosing Regimens by First Stable LXB Dosing Regimen Cohort



[a]In accordance with the US prescribing information. [b]Not mutually exclusive. The number of unique individuals was 14,584. [c]In accordance with the US prescribing information (for ≤6 g). LXB, low-sodium oxybate.

- Individuals were allocated into dosing regimen cohorts based on the first stable LXB dosing regimen. Of 14,613 individuals analyzed in 5 dosing regimen cohorts (which included 14,584 unique individuals), the most commonly prescribed LXB dosing regimen was total nightly dosage ≤9 g split twice nightly in 13,318 individuals (91.1%; narcolepsy, n=10,861; IH, n=2457)

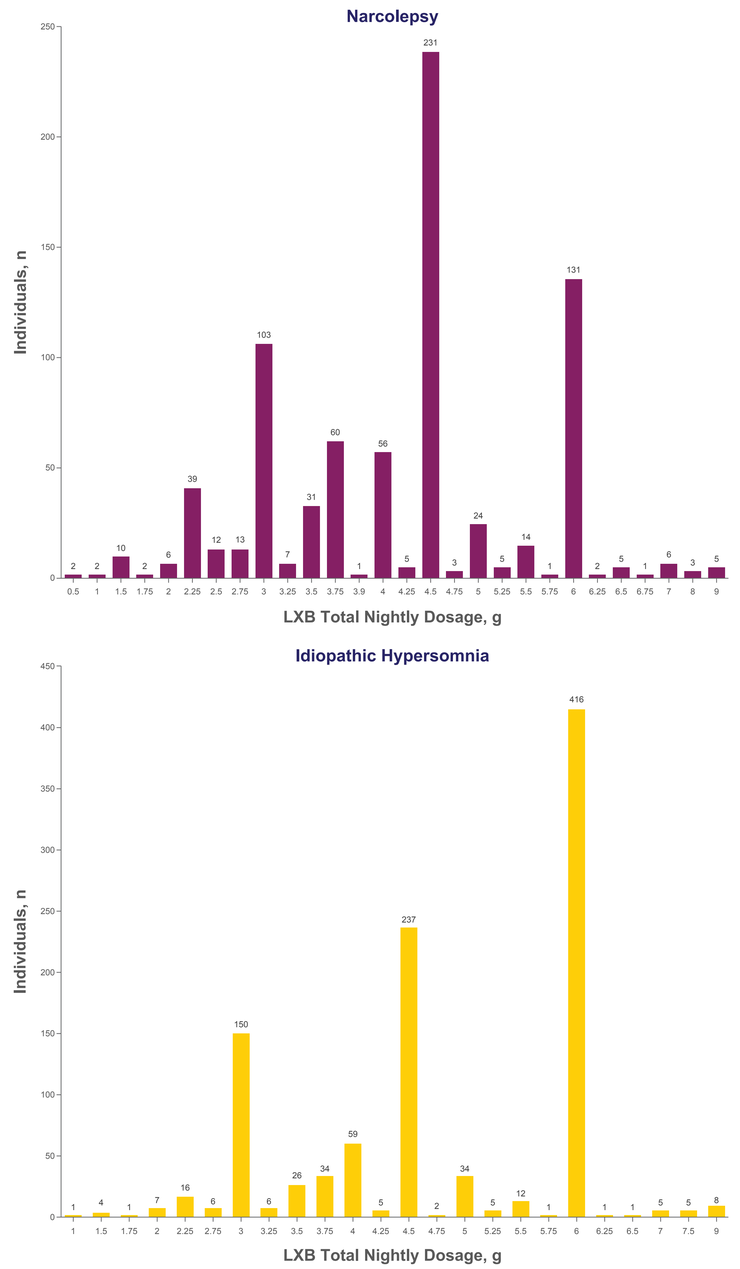
Table 1. Demographics and Clinical Characteristics of Individuals by First Stable LXB Dosing Regimen Cohort[a]

Parameter	Any Once-Nightly Regimen		>9 g Total Nightly Dosage[c] (n=127)	≥3 Nightly Doses[c] (n=91)	LXB ≤9 g Dosage Twice Nightly[c,d] (n=13,318)
	Narcolepsy (n=297)	Idiopathic Hypersomnia[b] (n=780)			
Age, mean (SD), years	39.3 (14.51)	38.2 (12.94)	45.3 (12.63)	43.7 (13.85)	38.9 (12.91)
Sex, % Male / Female	30.3 / 69.7	28.7 / 71.3	44.9 / 55.1	27.5 / 72.5	32.2 / 67.8
First available diagnosis, % Narcolepsy / Idiopathic Hypersomnia	100 /	100 /	11.8 / 88.2	11.0 / 89.0	18.4 / 81.6

[a]The number of unique individuals was 14,584; an individual could have been in more than one dosing regimen cohort. [b]Once-nightly LXB ≤6 g is in accordance with the US prescribing information for idiopathic hypersomnia. [c]Narcolepsy or idiopathic hypersomnia. [d]In accordance with the US prescribing information for both narcolepsy and idiopathic hypersomnia indications.
LXB, low-sodium oxybate; SD, standard deviation.

- Compared with the individuals who were prescribed LXB ≤9 g dosage twice nightly:
  - Individuals prescribed total >9 g/night dosage were more frequently male (44.9% vs 32.2% in the LXB ≤9 g twice-nightly cohort) and their mean age was numerically higher (45.3 years vs 38.9 years in the LXB ≤9 g twice-nightly cohort)
  - Individuals prescribed ≥3 nightly doses were slightly older (43.7 years vs 38.9 years)
- The distribution of equal vs unequal doses for individuals taking twice-nightly LXB was:
  - >9 g total nightly dosage: 69.3% vs 30.7%, respectively
  - ≥3 nightly doses: 69.2% vs 30.8%, respectively
  - ≤9 g dosage twice nightly: 92.6% vs 7.4%, respectively

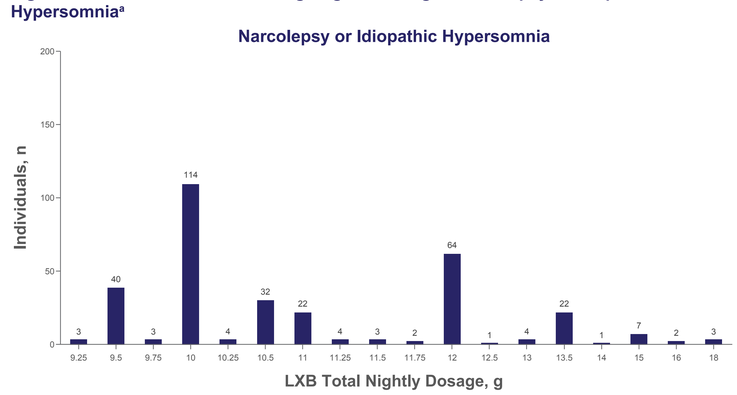
Figure 2. Distribution of Once-Nightly LXB Dosing Regimens by Narcolepsy or Idiopathic Hypersomnia[a]



[a]Among individuals across any stable LXB dosing regimen (including first stable regimen and subsequent stable regimens). Each LXB total nightly dosage received for >90 days is counted. Each data point represents an individual on a stable dosing regimen. An individual could have been counted in more than one category.
LXB, low-sodium oxybate.

- The most frequently prescribed once-nightly dosing regimens were 4.5 g for narcolepsy and 6 g for idiopathic hypersomnia

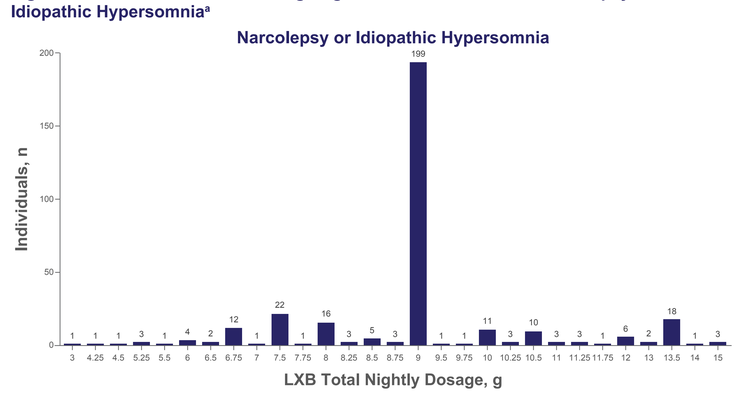
Figure 3. Distribution of LXB Dosing Regimens >9 g in Narcolepsy or Idiopathic Hypersomnia[a]



[a]Among individuals across any stable LXB dosing regimen (including first stable regimen and subsequent stable regimens). Each LXB total nightly dosage received for >90 days is counted. Each data point represents an individual on a stable dosing regimen. An individual could have been counted in more than one category.
LXB, low-sodium oxybate.

- The most frequently prescribed LXB dosing regimens >9 g were 9.5 g, 10 g, and 12 g (more than one LXB total nightly dosage category)

Figure 4. Distribution of LXB Dosing Regimens With ≥3 Doses in Narcolepsy or Idiopathic Hypersomnia[a]



[a]Among individuals across any stable LXB dosing regimen (including first stable regimen and subsequent stable regimens). Each LXB total nightly dosage received for >90 days is counted. Each data point represents an individual on a stable dosing regimen. An individual could have been counted in more than one category.
LXB, low-sodium oxybate.

- The most frequently prescribed dosing regimen split into ≥3 doses was 9 g