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Individualized Dosing With Low-Sodium Oxybate in Idiopathic Hypersomnia: Patient Voices From LYRICAL

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Objective

- To describe low-sodium oxybate (LXB) dosing patterns (including equal or unequal dose division, timing, and titration), adjustments to dosing regimens since enrollment, and perceptions of individualized dosing among LYRICAL participants with idiopathic hypersomnia

Conclusions

- Real-world data from LYRICAL underscore the importance of individualized LXB dosing from the patient perspective and shared decision-making between patients and their healthcare providers
- Limitations include the lack of a comparator group, potential selection and recall bias (participants had been taking LXB for ≥12 weeks at enrollment), and small sample sizes for some analyses
- LXB dosing adjustments were associated with improved ratings of treatment convenience and effectiveness

References: 1. Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution, CIII [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.

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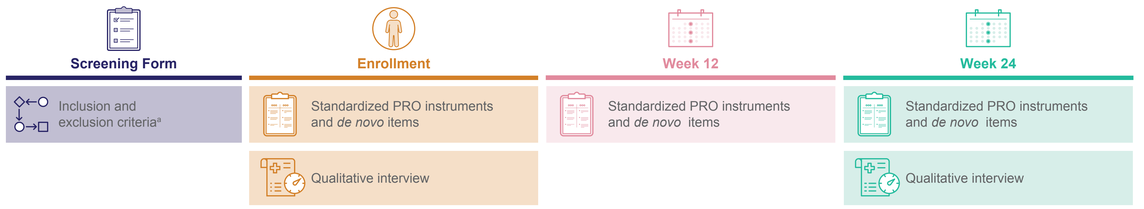
Introduction

- Low-sodium oxybate (LXB; Xywav®) is approved by the US Food and Drug Administration for the treatment of excessive daytime sleepiness or cataplexy in patients 7 years of age or older with narcolepsy and for the treatment of idiopathic hypersomnia in adults[1]
  - For patients with idiopathic hypersomnia, LXB is an oral solution taken once or twice nightly, in equally or unequally divided doses, administered at bedtime and 2.5 to 4 hours later; the dosage can be individually optimized based on efficacy and tolerability through gradual titration up to the maximum recommended dosage of 6 g (once nightly) or 9 g (twice nightly)
- Since the approval of LXB, limited real-world evidence has been published on how LXB individualized dosing may relate to treatment satisfaction from the patient perspective, particularly in idiopathic hypersomnia. The LYRICAL (**L**ongitudinal mixed methods stud**Y** of **R**eal-world patterns of use, effectiveness, and treatment satisfaction in adults with **I**diopathic hypersomnia and nar**C**olepsy t**A**king **L**ow-sodium oxybate) study was conducted to better understand the real-world experience of adults with narcolepsy or idiopathic hypersomnia taking LXB treatment
  - This poster reports results describing LXB individualized dosing for participants with idiopathic hypersomnia; LXB individualized dosing results for the narcolepsy cohort are presented in **Poster 362**
  - **Posters 359** and **360** describe participant-reported effectiveness and treatment satisfaction for LYRICAL participants with narcolepsy and idiopathic hypersomnia, respectively; **Posters 534** and **535** explore associations between daytime and nighttime symptoms and quality-of-life outcomes for LYRICAL participants with narcolepsy and idiopathic hypersomnia, respectively
  - **Poster 528** explores LXB individualized dosing among participants with narcolepsy and idiopathic hypersomnia in the phase 4, prospective, single-arm, open-label DUET study

Methods

- This longitudinal, mixed-methods study gathered quantitative (survey) and qualitative (interview) data from participants currently taking LXB at enrollment and over the 24-week study period

Figure 1. LYRICAL Study Design

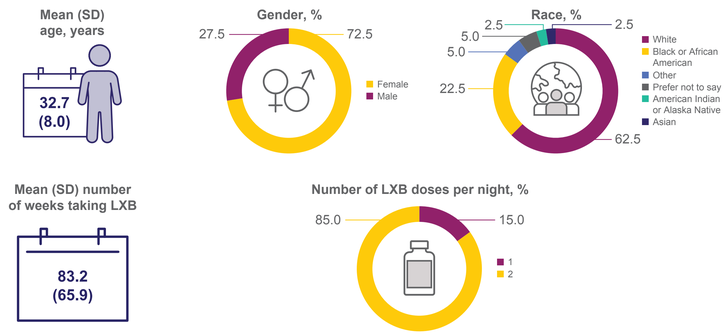


[a]Participants were eligible if they were ≥18 years of age at the time the screening form was completed; a US resident; diagnosed with narcolepsy or idiopathic hypersomnia; prescribed and currently taking LXB for narcolepsy or idiopathic hypersomnia; and had been taking LXB for ≥12 weeks prior to screening. All participants provided written or electronic informed consent.
LXB, low-sodium oxybate; PRO, patient-reported outcome.

- Online surveys were conducted between March 2024 and August 2025 via an IQVIA-hosted platform, and comprised standardized patient-reported outcome instruments (eg, 9-item Treatment Satisfaction Questionnaire for Medication [TSQM-9]) and *de novo* questions assessing LXB dosing patterns; surveys were administered at enrollment, week 12, and week 24
- Virtual, 45-minute interviews were conducted using semi-structured discussion guides with a subset of participants at enrollment (n=13) and week 24 (n=12)
  - Interviews were audio-recorded, transcribed, and coded and analyzed using MAXQDA (VERBI Software, 2021) and Microsoft Excel
- Descriptive analyses were conducted

Results

Figure 2. Characteristics of Participants With Idiopathic Hypersomnia

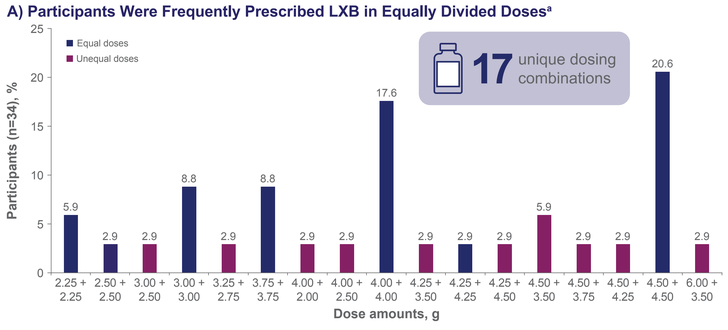


LXB, low sodium oxybate; SD, standard deviation.

- Among 40 participants with idiopathic hypersomnia, the mean (SD) age was 32.7 (8.0) years
- The majority of participants were female (72.5%) and White (62.5%)
- The mean (SD) duration of LXB treatment was 83.2 (65.9) weeks; 85.0% of participants were taking LXB twice nightly and 15.0% were taking a once-nightly regimen
- The mean (SD) total nightly dosage was 7.3 (2.0) g
- Additional participant characteristics are reported in the Supplement, accessed via the QR code

Figure 3. LXB Dosing Patterns for Participants Taking LXB Twice Nightly at Enrollment

A) Participants Were Frequently Prescribed LXB in Equally Divided Doses[a]



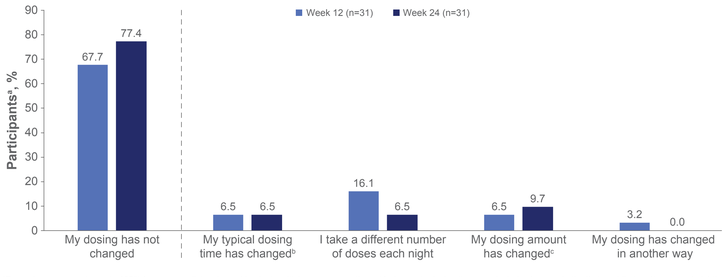
B) Participants Described Reasons for Being Prescribed Unequally Divided LXB Doses[b]

Reasons for Unequally Divided Dosing	Participants (n=11)
To help stay asleep	5
To help fall asleep	3
To avoid feeling groggy in the morning	2
To improve sleep quality	2
To avoid nausea	1
To avoid headaches	1
Other[c]	6

[a]Six participants who reported taking LXB once nightly are not shown. [b]Each icon represents 1 participant. Participants could select multiple response options. [c]Examples of "other" reasons included "to avoid oversleeping," "to avoid vertigo," and "to minimize the likelihood of LXB having an effect on waking."
LXB, low-sodium oxybate.

- Among the 34 participants taking LXB twice nightly (85.0%), 17 unique dosing combinations were utilized
  - Eleven (32.4%) participants took unequally divided doses at enrollment, typically with a lower second dose, to support specific individual needs

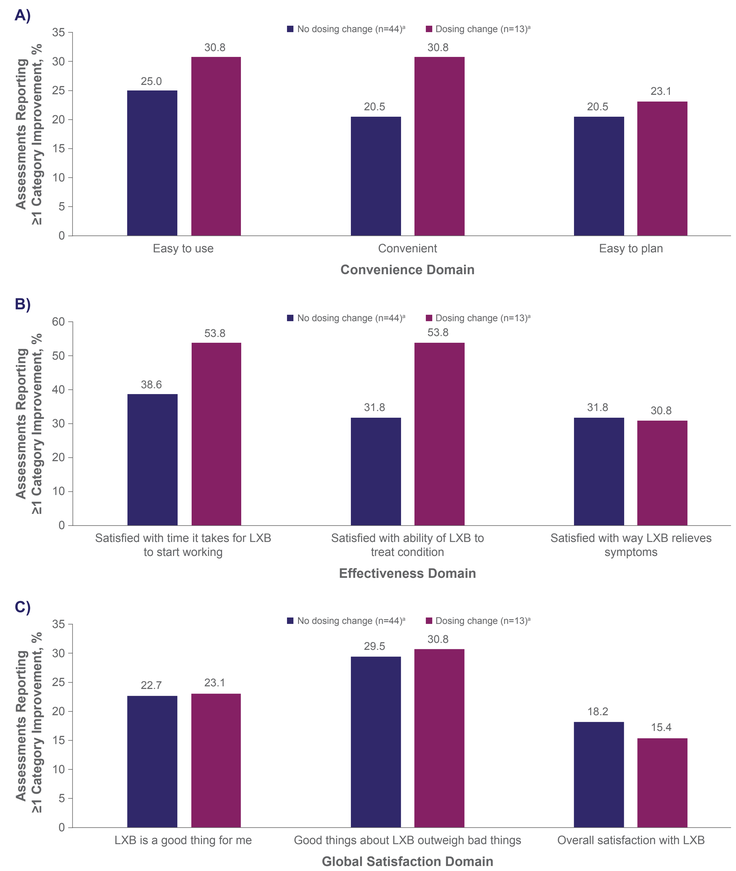
Figure 4. Most Participants Did Not Have an LXB Dosing Change Since Enrollment



[a]Percentages may not sum to 100% because participants could select multiple response options. [b]A change in dosing time may include changes to the timing of first and/or second nightly doses. [c]A change in dosing amount may include changes to individual dose amounts and/or a change in total nightly dosage.

- Of the 35 participants with dosing change data, 9 (25.7%) reported a change to their LXB dosing regimen, in consultation with their healthcare provider, at weeks 12 or 24
- Among the 9 participants who reported LXB dosing changes, the most common adjustments were a change to the number of nightly doses taken and a change in dosing amount

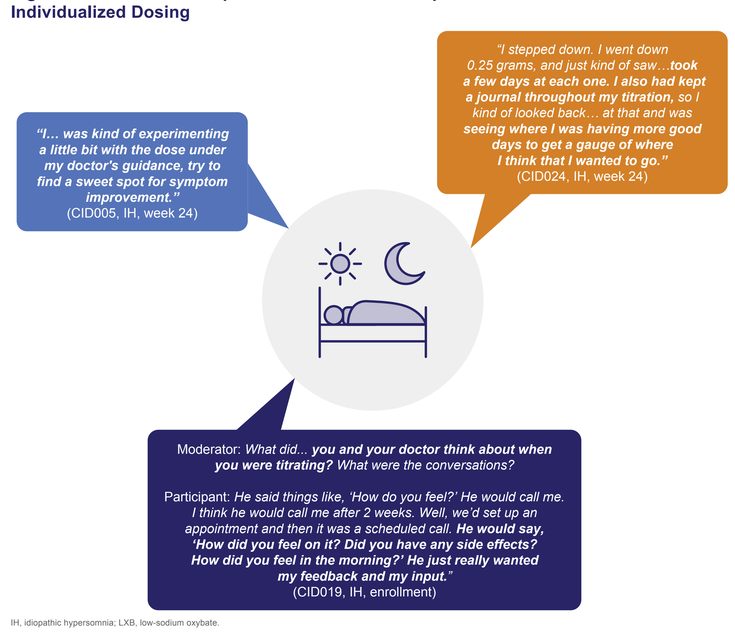
Figure 5. Improvements in TSQM-9 Response Categories From Enrollment to Weeks 12 or 24, Among Those With and Without an LXB Dosing Change[a,b]



[a]The 9 participants who had LXB dosing regimen adjustments at weeks 12 or 24 contributed 13 follow-up assessments; 44 follow-up assessments were contributed by 29 participants who did not have a dosing change. As there were 2 follow-up timepoints, a participant could report no dosing change at week 12 and still confirm a dosing change at week 24. Percentages reflect the proportion of follow-up assessments, as opposed to the proportion of participants. [b]Results indicate improvement of at least 1 response category (eg, from "satisfied" to "very satisfied").
LXB, low-sodium oxybate; TSQM-9, 9-item Treatment Satisfaction Questionnaire for Medication.

- Overall, improvements in treatment satisfaction were reported over time among participants
- Participants who adjusted their LXB dosing regimens more frequently reported improvements in treatment convenience and effectiveness than those without dosing changes

Figure 6. Interview Participants Described Their Experience With LXB Titration and Individualized Dosing



IH, idiopathic hypersomnia; LXB, low-sodium oxybate.

- At enrollment, all 13 interview participants reported shared decision-making with healthcare providers
  - The most common consideration for dose adjustment during titration was slower titration (53.8%)
- In interviews at enrollment and week 24, 8 of 11 (72.7%) and 9 of 10 (90.0%) participants, respectively, reported that individualized dosing was helpful for their lifestyle

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Supplemental Results

Supplemental Table S1. Additional Participant Characteristics

Characteristic	Participants With Idiopathic Hypersomnia (N=40)
Age (years)	
Mean (SD)	32.7 (8.0)
Median (range)	30.5 (21, 53)
Gender, n (%)	
Female	29 (72.5)
Male	11 (27.5)
Race, n (%)	
White	25 (62.5)
Black or African American	9 (22.5)
Prefer not to answer	2 (5.0)
Other	2 (5.0)
American Indian or Alaska Native	1 (2.5)
Asian	1 (2.5)
Employment, n (%)[a]	
Working full-time	26 (65.0)
Student	6 (15.0)
Seeking work opportunities	2 (5.0)
Working part-time	6 (15.0)
Homemaker	3 (7.5)
Unable to work	3 (7.5)
Number of LXB doses per night, n (%)	
1	6 (15.0)
2	34 (85.0)
Number of weeks taking LXB	
Mean (SD)	83.2 (65.9)
ESS score	
Mean (SD)	10.7 (5.3)
Other current comorbid diagnoses, n (%)[a]	
Attention deficit disorder/attention deficit hyperactivity disorder	6 (15.0)
Anxiety	18 (45.0)
Depression	12 (30.0)
Hypertension	1 (2.5)
Obesity	3 (12.5)
Obstructive sleep apnea	5 (12.5)
Periodic limb movement disorder	2 (5.0)
Restless legs syndrome	1 (2.5)
Current concomitant treatments, n (%)[a]	
Amphetamine	10 (25.0)
Armodafinil	1 (2.5)
Fluoxetine	4 (10.0)
Methylphenidate	7 (17.5)
Modafinil	3 (7.5)
Pitolisant	1 (2.5)
Sertraline	2 (5.0)
Solriamfetol	5 (12.5)
Other current treatment	4 (10.0)
None of the above[b]	16 (40.0)

[a]Response options are not mutually exclusive. [b]"None of the above" indicates participants were not taking any of the medications listed in this table; however, they may have been taking other concomitant medications.
ESS, Epworth Sleepiness Scale; LXB, low-sodium oxybate; SD, standard deviation.