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Dosing and Reasons for Transitioning From Sodium Oxybate to Lower-Sodium Oxybate in People With Narcolepsy: Data From the Real-World TENOR Study

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Introduction

- Lower-sodium oxybate (LXB; Xywav®) is an oxybate medication, containing 92% less sodium than sodium oxybate (SXB; Xyrem®), that is approved by the US Food and Drug Administration (FDA) for treating cataplexy or excessive daytime sleepiness in patients with narcolepsy ≥7 years of age and for treating idiopathic hypersomnia in adults[1,2]
  - LXB has been recognized by the FDA in the narcolepsy population for its significant reduction in chronic sodium burden compared with SXB, which "will be clinically meaningful in reducing cardiovascular morbidity in a substantial proportion of patients for whom the drug is indicated"[3]
- When transitioning from SXB to LXB, the recommendation is to initiate LXB treatment at the same dose and regimen as SXB (gram-for-gram) and titrate based on efficacy and tolerability, if necessary[1]
- Controlled clinical trial data have demonstrated successful transitions from SXB to LXB[1,2]; however, real-world data are needed to inform expectations of the patient population and medical community regarding transitioning from SXB to LXB
- The *Transition Experience of persons with Narcolepsy taking Oxybate in the Real-world* (TENOR) study examined the impact of transitioning from SXB to LXB in a real-world setting

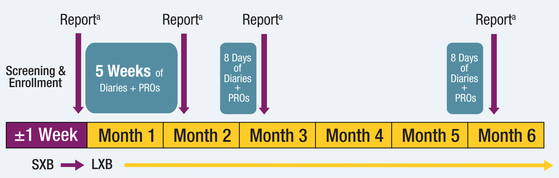
Objective

- This analysis evaluated characteristics and dosing strategies of patients with narcolepsy who transitioned from SXB to LXB in TENOR

Methods

- TENOR was a patient-centric, prospective, observational, noninterventional, virtual-format study (NCT04803786)
- Eligible participants included US adults with confirmed narcolepsy (type 1 or 2) transitioning from SXB to LXB within the previous or upcoming 7 days
- Longitudinal data were collected for 21 weeks post-transition (including data collected at initiation of LXB treatment) via daily and weekly diaries and questionnaires completed by participants
- These analyses comprise an interim data cut (as of October 13, 2021) and include baseline data (taking SXB) from all enrolled participants and 1-week follow-up data (taking LXB) for those who had completed this timepoint
- Continuous variables were summarized with descriptive statistics (n, mean, standard deviation [SD], median, quartiles, minimum, and maximum); frequency counts and percentage of participants within each category were provided for categorical data

Figure 1. Study Design



LXB, lower-sodium oxybate; PRO, patient-reported outcome; SXB, sodium oxybate.
[a]Each participant engagement report includes a different combination of personal, aggregate, and study-related data.

References
1. XYWAV® (calcium, magnesium, potassium, and sodium oxybates) oral solution, CIII [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals.
2. Bogan RK, et al. *Sleep*. 2021;44:zsaa206.
3. Food and Drug Administration. Clinical superiority findings. 2021. Available at: https://www.fda.gov/industry/designating-orphan-product-drugs-and-biological-products/clinical-superiority-findings.

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Results

Table 2. Dosing Regimens for SXB and LXB

Characteristic	SXB Dose N=85	Starting LXB Dose n=84	LXB Dose After 1 Week n=79
Doses per night, n (%)			
1	2 (2.4)	1 (1.2)	1 (1.3)
2	82 (96.5)	82 (97.6)	77 (97.5)
3	1 (1.2)	1 (1.2)	1 (1.3)
Dosing strategy for twice-nightly regimens, n (%)			
Equal doses	72 (87.8)	73 (89.0)	68 (88.3)
Unequal doses: first dose higher	9 (11.0)	7 (8.5)	6 (7.8)
Unequal doses: second dose higher	1 (1.2)	2 (2.4)	3 (3.9)
Total nightly dose, g			
Mean (SD)	7.7 (1.5)	7.7 (1.5)	7.8 (1.5)
Median (Q1, Q3)	8.0 (7.0, 9.0)	8.0 (6.6, 9.0)	8.0 (6.8, 9.0)
Min, Max	4, 12	5, 12	5, 12
≤4.5 g, n (%)	5 (5.9)	6 (7.1)	5 (6.3)
>4.5 to ≤6.0 g, n (%)	13 (15.3)	13 (15.5)	11 (13.9)
>6.0 to ≤7.5 g, n (%)	19 (22.4)	18 (21.4)	19 (24.1)
>7.5 to ≤9.0 g, n (%)	47 (55.3)	46 (54.8)	43 (54.4)
>9.0 g, n (%)	1 (1.2)	1 (1.2)	1 (1.3)

LXB, lower sodium oxybate; Q1, quartile 1; Q3, quartile 3; SD, standard deviation; SXB, sodium oxybate.

- The SXB dose and starting LXB dose were gram-for-gram in 87% of participants
- Dosing regimens were similar before, during, and 1 week after transition from SXB to LXB
  - Five (6%) participants reported an LXB dosing change after transitioning (1 increased dose, 3 decreased dose, and 1 changed to unequal doses)

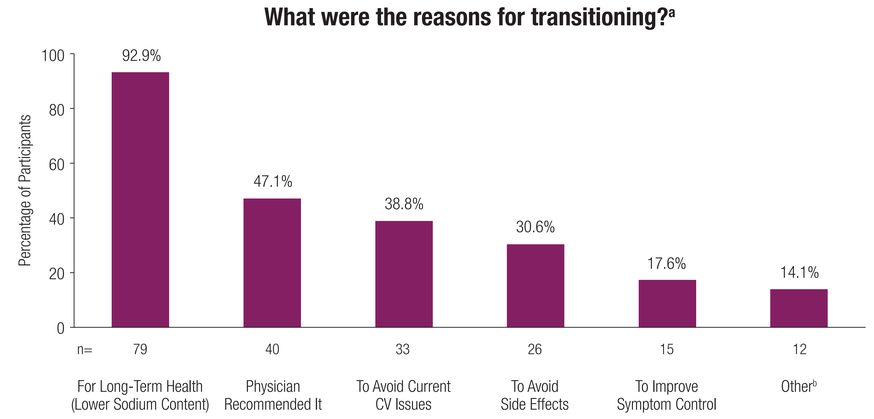
Table 1. Participant Demographics

Characteristics	Total N=85
Age, years, mean (SD)	40.3 (13.0)
Female, n (%)	62 (72.9)
BMI, kg/m^2, mean (SD)	28.0 (9.6)
Ethnicity, n (%)	
Hispanic, Latino, or Spanish origin	5 (5.9)
Not Hispanic, Latino, or Spanish origin	80 (94.1)
Race, n (%)[a]	
American Indian or Alaska Native	3 (3.5)
Asian	4 (4.7)
Black or African American	6 (7.1)
White	74 (87.1)
Other	5 (5.9)
Current employment status, n (%)[a]	
Employed full-time	46 (54.1)
Employed part-time	10 (11.8)
Unemployed	7 (8.2)
Student	13 (15.3)
Homemaker	8 (9.4)
Retired	8 (9.4)
Geographic region (United States), n (%)	
Midwest	19 (22.4)
Northeast	15 (17.6)
South	39 (45.9)
West	12 (14.1)

BMI, body mass index; SD, standard deviation.
[a]Selection of multiple categories was allowed; percentages may sum to greater than 100%.

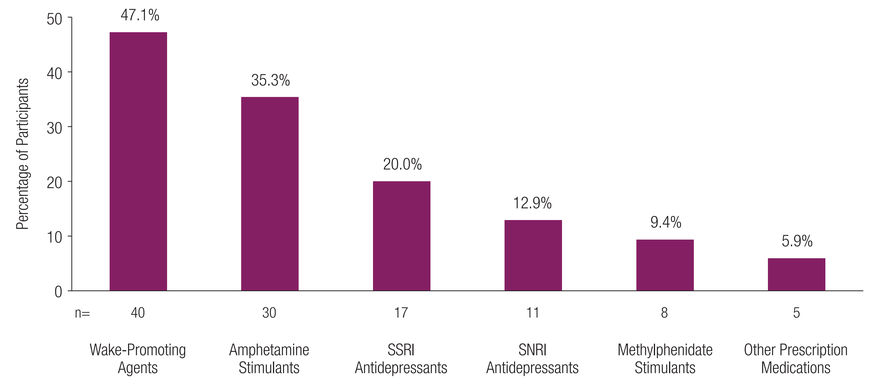
- This analysis included 85 participants (narcolepsy type 1, n=45; narcolepsy type 2, n=40) at baseline and 79 participants (narcolepsy type 1, n=42; narcolepsy type 2, n=37) at week 1
- At baseline, most participants took ≥1 concomitant medication for narcolepsy (79%) in addition to SXB
- Participants had been taking their current SXB treatment episode for a median (interquartile range) of 48 (15.0–75.0) months (self-reported)

Figure 2. Most Participants Switched for Long-term Health Reasons, Due to the Lower Sodium Content of LXB



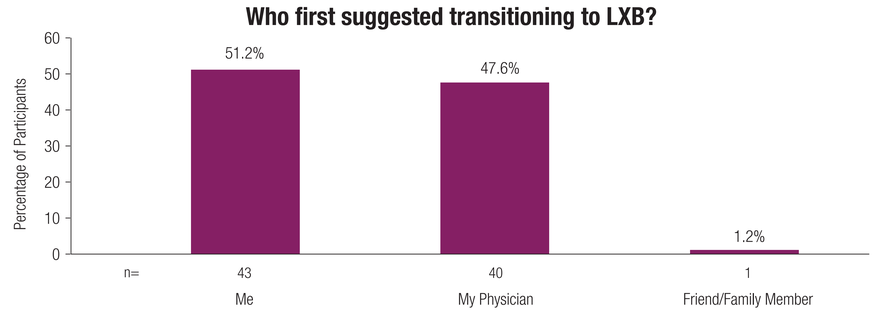
CV, cardiovascular; LXB, lower-sodium oxybate.
[a]Participants could select more than 1 reason.
[b]Other reasons varied widely and included hydration, high sodium, constipation, joint pain, swelling, and insurance coverage.

Figure 3. Wake-Promoting Agents and Amphetamine Stimulants Were the Most Common Concomitant Narcolepsy Medications Taken by Participants at Baseline With SXB



SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor; SXB, sodium oxybate.

Figure 4. Transition to LXB Was Mostly Initiated by Participants or Their Physicians



LXB, lower sodium oxybate.

Conclusions

- At week 1, the majority of TENOR participants transitioned from SXB to LXB using a gram-for-gram dose conversion
- Participants, as well as their physicians, prompted transitioning from SXB to LXB
- The most common reason for switching was for long-term health due to the lower sodium content of LXB

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