

Title: Patient-Reported Sleep Quality in People With Narcolepsy Transitioning From Sodium Oxybate to Lower-Sodium Oxybate

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Yes ___

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ABSTRACT

Introduction: Lower-sodium oxybate (LXB; Xyvav[®]), which contains the same active moiety as higher-sodium oxybate (SXB; Xyrem[®]) but with 92% less sodium, is approved by the US Food and Drug Administration (FDA) for treating cataplexy or excessive daytime sleepiness in patients ≥ 7 years of age with narcolepsy. LXB is recognized as clinically superior to SXB in narcolepsy by the US FDA due to lower chronic sodium exposure. Real-world data related to sleep quality following transition from SXB to LXB are lacking.

Methods: Transition Experience of persons with Narcolepsy taking Oxybate in the Real-world (TENOR; NCT04803786) was a patient-centric, prospective, observational, noninterventional, virtual-format study of US adults with narcolepsy (type 1 or 2) transitioning from SXB to LXB within the previous/upcoming 7 days. Longitudinal data collected during transition and for 21 weeks thereafter were based on daily and weekly questionnaires and sleep diaries instructing participants to rate the quality of their sleep and how refreshed they felt upon waking, and to record their sleep latency, wake after sleep onset (WASO), time in bed (TIB), and total sleep time (TST).

Results: The mean (standard deviation [SD]) age of the 85 participants (narcolepsy type 1, n=45; narcolepsy type 2, n=40) was 40.3 (13.0) years; most were female (73%) and White (87%). Almost all participants took SXB (82/85, 96%) twice nightly prior to transition and LXB (82/84, 98%) twice nightly after transition. Most participants rated their sleep quality as “good” or “very good” at baseline (45/84, 54%) and end of study (38/71, 54%), while 24/84 (29%) and 30/71 (42%) reported feeling “well-rested” or “very well-rested” at baseline and end of study, respectively. At end of study, changes (n=71)

in mean (SD) sleep latency, WASO, TIB, and TST were –10.5 (16.2), –14.8 (56.6), 7.6 (67.7), and 33.0 (93.8) minutes, respectively.

Conclusion: Although participant-reported sleep quality was generally unchanged during the study, a greater percentage of participants reported feeling refreshed at end of study (on LXB) than at baseline (on SXB); however, there was no non-transitioning arm for comparison. Small changes were noted at end of study in sleep parameters, including sleep latency, WASO, and TST.

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