

Lower-sodium oxybate (Xywav®) : Adis Evaluation

Clinical Considerations

- A novel oxybate formulation with same active moiety and 92% less sodium content than sodium oxybate
- First drug approved for the treatment of idiopathic hypersomnia in adults
- Effectively improves excessive daytime sleepiness and cataplexy in adults and children with narcolepsy and idiopathic hypersomnia-related symptoms in adults
- Demonstrates significant improvement on health related quality of life outcomes
- Generally well tolerated

Plain Language Summary

Background and rationale

- Narcolepsy and idiopathic hypersomnia are rare, chronic sleep disorders that can debilitate patients' cognitive function, social functioning and health-related quality of life. They are primarily characterized by excessive daytime sleepiness (EDS) and often require long-term (even life-long) treatment to reduce symptoms and improve functioning
- Sodium oxybate (Xyrem®) is an effective treatment option for EDS and cataplexy in patients with narcolepsy; however, its high sodium content may put patients at higher risk of increased blood pressure and cardiovascular disease.
- To reduce the excessive sodium intake associated with long-term therapy, lower-sodium oxybate (Xywav®), a new oxybate formulation with 92% less sodium content, has been developed
- In the USA, it is approved for the treatment of cataplexy or EDS in adults and children aged ≥ 7 years with narcolepsy, and is the first drug approved for the treatment of idiopathic hypersomnia in adults

Clinical findings

- In pivotal phase 3 trials, following dose titration and optimization periods, participants randomized to discontinue lower-sodium oxybate and take placebo showed significant worsening in narcolepsy- and idiopathic hypersomnia-related symptoms, as well as health-related quality of life outcomes compared to participants who continued taking lower-sodium oxybate
- Lower-sodium oxybate is generally well tolerated, with its safety profile similar to that of sodium oxybate

Conclusion

Lower-sodium oxybate is a valuable treatment option for children and adults with narcolepsy and adults with idiopathic hypersomnia

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