CNS Drugs

PEER-REVIEWED FEATURE

Daridorexant: Adis Evaluation

Clinical Considerations

- Orally administered dual orexin receptor antagonist
- Improves sleep onset, sleep maintenance and sleep time parameters, as well as daytime functioning, in adult and elderly patients
- Generally well tolerated
- Efficacy and tolerability are maintained longer-term (12 months) with no new safety concerns

Plain Language Summary

Background and rationale

- Insomnia disorder is characterized by persistent difficulty falling asleep and/or maintaining sleep and impaired daytime functioning
- Dual orexin receptor antagonists suppress wakefulness and are generally considered to have a favourable safety profile compared with older classes of insomnia drugs, including less risk of tolerance, dependence, abuse and withdrawal effects
- Daridorexant (Quviviq™) is the first dual orexin receptor antagonist approved for the treatment of chronic insomnia in the EU and has been approved for insomnia in the USA

Clinical findings

- In clinical trials, daridorexant improved objective sleep onset, objective sleep maintenance and self-reported total sleep time, and self-reported daytime functioning at a 50 mg dose
- Daridorexant was generally well tolerated, with a low incidence of adverse events such as sleepiness, fatigue, dizziness and falls, most of which were similar to that with placebo
- The efficacy and tolerability of daridorexant were sustained for 12 months

Conclusion

With a favourable safety profile compared to other classes of insomnia drugs, minimal residual next-morning effects and improvements in daytime functioning, daridorexant is a useful option for the treatment of insomnia disorder

Nie, T., Blair, H. A. CNS Drugs. 2023. https://doi.org/10.1007/s40263-023-00987-9