For patients with chronic insomnia.[1]

Restorative sleep

with QUVIVIQ™ (daridorexant) 50 mg[1–4]

Revitalized days

2023 EUROPEAN INSOMNIA GUIDELINE Recommended*[5]

QUVIVIQ™ is indicated for the treatment of adult patients with insomnia characterized by symptoms present for at least 3 months and considerable impact on daytime functioning.[1] This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the Summary of Product Characteristics for how to report adverse reactions.

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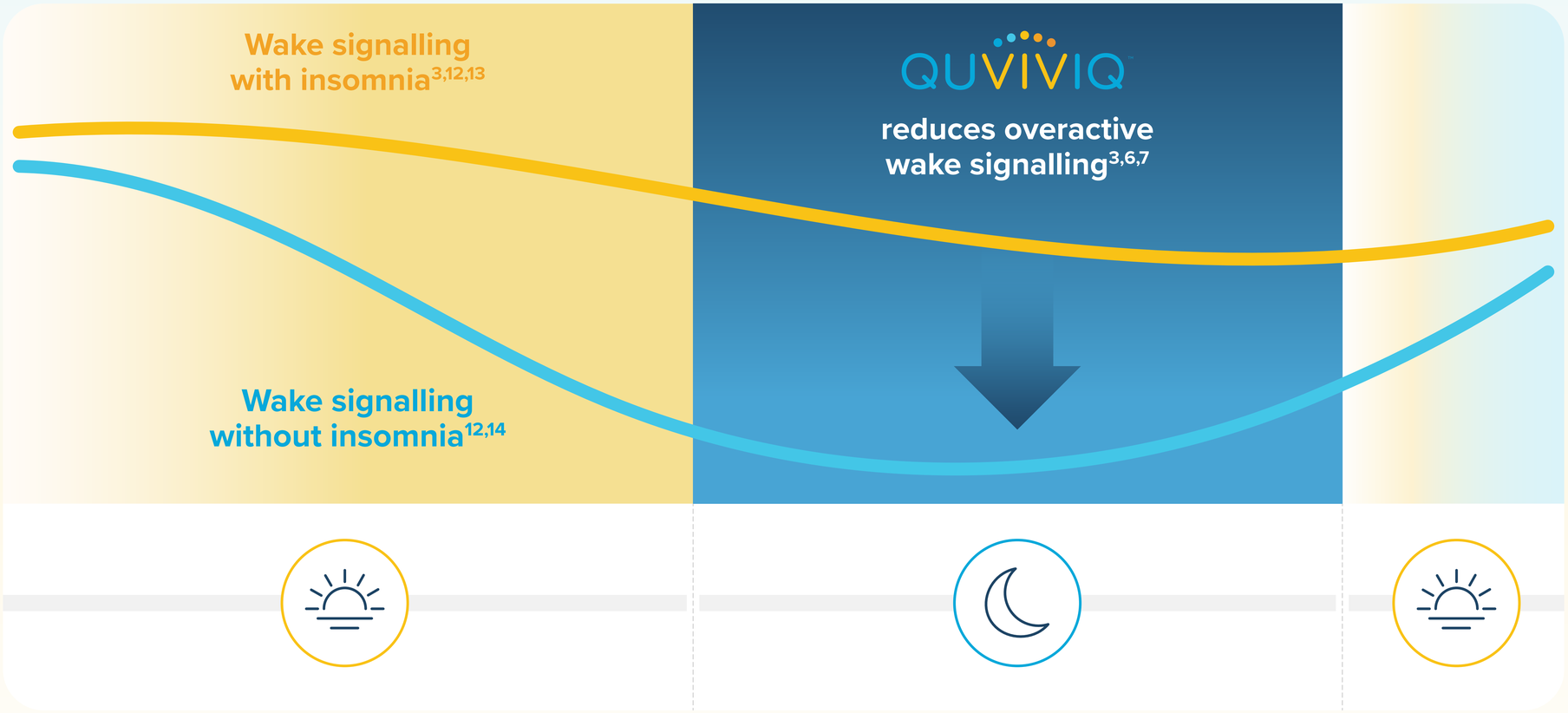
EUC-DA-00161 - June 2025

QUVIVIQ™ daridorexant 25mg, 50mg tablets

QUVIVIQ™: a different approach to treating chronic insomnia[1,6]

Multiple studies suggest **that wake-promoting regions of the brain remain overactive at night.**
This is known as hyperarousal.[7–10]

QUVIVIQ™ reduces overactive wake signaling by blocking orexin, a neurotransmitter that promotes wakefulness,[1,11] **allowing restorative sleep to occur** without altering the proportion of sleep stages.[1–3,6,12]



Graph not representative of sleep stages.

Help give your patients restorative sleep and revitalized days

Administration of QUVIVIQ™ 50 mg every night helps patients:†[2,4,6,16]

Restorative sleep

+1 hour

Stay asleep longer and fall asleep faster, **gaining an extra hour of sleep**, as measured by PSG[‡§]

8 hours

Reduce overactive wake signalling throughout the night

~1 hour

Increase their **self-reported** total sleep time on average by **~1 extra hour** each night[‖]

Revitalized days

Feel less tired¶

Feel less sleepy¶

Feel more energetic¶

Night and day efficacy can improve over time with consistent nightly use[2,4]

The recommended dose for adults is **50 mg taken every night**[**1]

Tablet not actual size.

- QUVIVIQ™ should be taken in the evening, within 30 minutes before bed[1]
- Time to sleep onset may be delayed if taken with or soon after a large meal[1]
- Patients should continue to practice good sleep habits[17]

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QUVIVIQ daridorexant 25mg,50mg tablets

Offer your patients a treatment that is well-tolerated over the long term[1,2,4]

No evidence of physical dependency...[1,4]

No evidence of abuse or withdrawal symptoms...[1,4]

No sign of rebound insomnia...[1,4]

...upon discontinuation of QUVIVIQ™ in an extension trial with up to 12 months of continuous nightly use[1,4]

QUVIVIQ™ 50 mg and placebo had comparable rates of AEs with up to 12 months of continuous treatment[2,4]

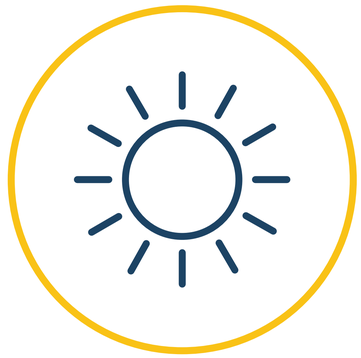
- At month 3 in clinical trials, headache and somnolence were the most commonly reported AEs for QUVIVIQ™ 50 mg[1,2]
- In a 12-month extension trial:
  - Headaches were reported in 2.2% of patients treated with QUVIVIQ™ 50 mg vs 1.6% with placebo[4]
  - Somnolence occurred in 2.9% of patients treated with QUVIVIQ™ 50 mg vs 0.0% with placebo[4]

There are no limitations to the treatment duration of QUVIVIQ™ if periodically reassessed, but should be used for as short a time as possible††1

Help restore your patients' nights and revitalize their days

Taken every night, QUVIVIQ™ 50 mg may help your patients:[1,2,4,16]

Increase total sleep time throughout the night[1,2,4,16]



Feel less tired, less sleepy and more energetic[1,2,4]

Experience no physical dependency‡‡§§[1,2,4]

Which of your patients with chronic insomnia disorder could benefit from restorative sleep and revitalized days with QUVIVIQ™ 50 mg?

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QUVIVIQ daridorexant 25mg,50mg tablets

* European Insomnia Guideline 2023 recommends QUVIVIQ™ as the only medicinal product with grade A evidence for treatment of chronic insomnia.

† On average at month 3 vs. baseline.[2]

‡ LPS (latency to persistent sleep): primary efficacy variable (objective), assessed by PSG. Results for the LSM variation from baseline vs. at 3 months (95% CI) for daridorexant 50 mg (n=310) vs. placebo (n=310): -35 (-38 to -31) vs. -23 (-26 to -20).[1]

§ WASO (wake after sleep onset): primary efficacy variable (objective), assessed by PSG. Results for the LSM variation from baseline vs. at 3 months (95% CI) for daridorexant 50 mg (n=310) vs. placebo (n=310): -29 (-33 to -25) vs. -11 (-15 to -7).[1]

‖ sTST (self-reported total sleep time): secondary efficacy variable (subjective). The improvement in total sleep time perceived by the patient was consistent with the objective measurement by PSG.[2] Results for the LSM variation from baseline at 3 months (95% CI) for daridorexant 50 mg (n=310) vs. placebo (n=310): 58 (51 to 64) vs. 38 (31 to 44).[1]

¶ IDSIQ: secondary efficacy variable (subjective). The data presented belong to the sleepiness domain of the IDSIQ. Results for the LSM variation from baseline vs.at 3 months (95% CI) for daridorexant 50 mg (n=310) vs. placebo (n=310): -1.9 (-2.9 to -0.9).[1,2]

** For patients with moderate hepatic impairment or taking moderate CYP3A4 inhibitors, 25 mg is recommended. In the case of co-administration with CNS-depressant medicinal products, dose adjustments of QUVIVIQ™ and/or the other medicinal products may be required, based on clinical evaluation, due to potentially additive effects. Use of QUVIVIQ™ is not recommended in patients with severe hepatic impairment.[1]

†† The treatment duration should be as short as possible. The appropriateness of continued treatment will be assessed within 3 months by your doctor and periodically thereafter.[1]

‡‡ QUVIVIQ™ has no treatment duration limit if periodically reassessed and should be used for as short a time as possible.

§§ Upon discontinuation of QUVIVIQ™ in an extension trial with up to 12 months of continuous nightly use.[1,2,4]

Abbreviations

AE, adverse event; CI, confidence interval; CNS, central nervous system; CYP3A4, Cytochrome P450 3A4; IDSIQ, Insomnia Daytime Symptoms and Impacts Questionnaire; LPS, latency to persistent sleep; LSM, least squares mean; PSG, polysomnography; sTST, self-reported total sleep time; WASO, wake after sleep onset.

References

1. QUVIVIQ™ Idorsia Pharmaceuticals LTD, summary of product characteristics, EMA. Available at: https://www.ema.europa.eu/en/documents/product-information/quviviq-epar-product-information_en.pdf. Last accessed: June 2025.
2. Mignot E, et al. Lancet Neurol. 2022; 21(2): 125–139.
3. Robbins R, et al. Front Sleep. 2022; 1: 9352282.
4. Kunz D, et al. CNS Drugs. 2023;37(1):93–106.
5. Riemann D, et al. J Sleep Res. 2023; 32(6): e14035.
6. Roch C, et al. Psychopharmacology. 2021; 238(10): 2693–2708.
7. Riemann D, et al. Sleep Med Rev. 2010; 14(1): 19–31.
8. Nofzinger E, et al. Am J Psychiatry. 2004; 161: 2126–2212.
9. Morin C, et al. Nat Rev Dis Primers. 2015; 1: 15026.
10. Buysse D, et al. Drug Discov Today Dis Models. 2011; 8(4): 129–137.
11. Saper C, et al. Nature. 2005; 437(7063): 1257–1263.
12. Di Marco T, et al. Sleep. 2024; 47(11):zsae098.'
13. Schwartz JRL, et al. Curr Neuropharmacol. 2008; 6(4): 367–378.
14. Young Oh D, et al. J Clin Med. 2020; 9(11): 3425.
15. Della Monica C, et al. Physiol News. 2018; (113): 36–39.
16. Di Marco T, et al. CNS Drugs. 2023; 37(7): 639–653.
17. Sleep Foundation. Sleep Hygiene. Available at: https://www.sleepfoundation.org/sleep-hygiene. Last accessed: June 2025.

Adverse events must be reported. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in section 4.8 of the SmPC. Optional, as per local requirements: local HA contact details for AE reporting (Appendix V).

Abbreviated Prescribing Information: QUVIVIQ™ (daridorexant)

Abbreviated Prescribing Information: QUVIVIQ® (daridorexant)
▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the Summary of Product Characteristics for how to report adverse reactions.
Important note: Before prescribing, consult the full SmPC. **Presentation** Daridorexant 25 mg and 50 mg film-coated tablets **Pharmacotherapeutic group / ATC code:** Psycholeptics, Orexin receptor antagonists / N05CJ03 **Therapeutic indication** QUVIVIQ is indicated for the treatment of adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning. **Posology and method of administration** Recommended dose: one tablet of 50 mg once per night, taken orally in the evening within 30 minutes before going to bed. For patients with moderate hepatic impairment, or taking moderate CYP3A4 inhibitors, or CNS depressants (based on clinical judgement) the recommended dose is 25 mg once per night. The treatment duration should be as short as possible. The appropriateness of continued treatment should be assessed within 3 months and periodically thereafter. **Contraindications** - Hypersensitivity to daridorexant or any of the excipients - Narcolepsy - Concomitant use with strong CYP3A4 inhibitors **Warnings and precautions for use** Use with caution in elderly patients because of the general risk of falls. Efficacy and safety data in patients >75 are limited. Patients should be cautioned about drinking alcohol during treatment. Sleep paralysis and hypnagogic/hypnopompic hallucinations can occur, mainly during the first weeks of treatment. Symptoms similar to mild cataplexy have been reported with dual orexin receptor antagonists. Prescribers should explain this to patients and should consider discontinuing in case events occur. Use with caution in patients exhibiting symptoms of depression. Use with caution in patients with psychiatric co-morbidities due to limited efficacy and safety data. Daridorexant did not have significant respiratory effects in patients with mild, moderate or severe OSA or moderate COPD. In the absence of data, use with caution in patients with and severe COPD. There was no evidence of abuse or withdrawal symptoms indicative of physical dependence upon treatment discontinuation in clinical studies with daridorexant in subjects with insomnia. Because individuals with a history of abuse or addiction to alcohol or other substances may be at increased risk for abuse of QUVIVIQ, these patients should be followed carefully. Use is not recommended in patients with severe hepatic impairment. **Interactions** The recommended dose is 25 mg when used with moderate CYP3A4 inhibitors. Contraindicated with strong CYP3A4 inhibitors. Use with moderate or strong CYP3A4 inducers may reduce efficacy. Caution should be used in case of simultaneous administration with CYP3A4 and P-gp substrates, with close monitoring in the case of medicinal products with a narrow therapeutic index. **Fertility, pregnancy and lactation** Use during pregnancy only if the clinical condition of the pregnant woman requires treatment with QUVIVIQ. The presence of daridorexant in breast milk is low. Avoid use during breast-feeding because a risk of excessive somnolence to the breastfed infant cannot be excluded. **Effects on availability to drive and use machines** Patients should be cautioned about engaging in potentially hazardous activities, driving, or operating heavy machinery unless they feel fully alert, especially in the first few days of treatment. In order to minimise this risk, a period of approximately 9 hours is recommended between taking QUVIVIQ and driving or using machines. **Undesirable effects** Common (≥ 1/100 to < 1/10): headache, somnolence, dizziness, nausea, fatigue. Consult the full SmPC for less common side effects. **Overdose** General symptomatic and supportive medical care should be provided, adverse reactions at supra-therapeutic doses may include somnolence, muscular weakness, disturbance in attention, fatigue, headache and constipation. **Packaging quantity and storage conditions** Blisters packed in cartons of 10, 20 or 30 film-coated tablets. No special storage conditions required. **Marketing Authorisation Holder and Numbers** Idorsia Pharmaceuticals Deutschland GmbH Marie-Curie-Strasse 8 79539 Lörrach Germany EU/1/22/1638/001-006 **Cost** *Local information - as per local requirements.* **Prescription conditions** *Local information on classification, prescription conditions, reimbursement, as applicable.* **Date of first authorisation / renewal of the authorisation** 29 April 2022 **Date of last revision of prescribing information** 09/2024 **Full prescribing information available from** https://www.idorsia.com/documents/com/label/quviviq-smpc.pdf For any additional information please contact the local representative.

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