Prescribing Information
Great Britain and Northern Ireland

QUVIVIQ ▼25 mg and 50 mg film-coated tablets (daridorexant)

Important note: Before prescribing, consult the full SmPC.

Presentation
Daridorexant 25 mg and 50 mg film-coated tablets

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. The maximum daily dose is 50 mg.

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. Clinical data are available for up to 12 months of continuous treatment.
If a dose is forgotten at bedtime, that dose should not be taken during the night. The consumption of grapefruit or grapefruit juice in the evening should be avoided.

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 although clinical studies did not show an increase in the incidence of falls on daridorexant compared to placebo. Efficacy and safety data in patients >75 are limited.

Patients should be cautioned about drinking alcohol during treatment.

Use with caution when prescribing with CNS-depressant medicinal products due to potentially additive effects and consider a dose adjustment of either QUVIVIQ or the CNS depressant.

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 treatment depending on the nature and severity of any events.

Use with caution in patients exhibiting symptoms of depression. Suicidal tendencies may be present in patients with depression and protective measures may be required.

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 to moderate or severe obstructive sleep apnoea (OSA) or moderate chronic obstructive pulmonary disease (COPD). In the absence of data, use with caution in patients with 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
Contraindicated with strong CYP3A4 inhibitors. Use with moderate or strong CYP3A4 inducers may reduce efficacy. Caution should be used in case of simultaneous administration of QUVIVIQ with sensitive substrates of CYP3A4, or of P-gp, with close monitoring in the case of medicinal products with a narrow therapeutic index (e.g. digoxin). The consumption of grapefruit or grapefruit juice in the evening should be avoided. Refer to full SmPC for further information on interactions.

Fertility, pregnancy and lactation
Use during pregnancy only if the clinical condition of the pregnant woman requires treatment with QUVIVIQ.
Available data indicates that the presence of daridorexant in breast milk is low. Consider discontinuing breast-feeding or QUVIVIQ because a risk of excessive somnolence to the breastfed infant cannot be excluded.

Effects on ability 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 further information on 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 or 30 film-coated tablets.

Marketing Authorisation Holder and Numbers
Idorsia Pharmaceuticals Deutschland GmbH
Marie-Curie-Strasse 8
79539 Lörrach
Germany

Great Britain: PLGB 48711/0002-0003
Northern Ireland: EU/1/22/1638/001-006

Cost
QUVIVIQ 25 mg x 30 tablets and QUVIVIQ 50 mg x 30 tablets: £42 per pack

Prescription conditions
Prescription only medicine.

Adverse events must be reported. Healthcare professionals are asked to report any suspected adverse reactions via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google play or Apple App store. Adverse events should also be reported to ds.safety.uk@idorsia.com

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