Daridorexant (Quviviq®▼) – for insomnia in adults

[darry-door-rex-ant]

Prescribing Support Series - 5

Local Formulary Status:
NENC: GREEN+ - approved for initiation via sleep clinics at JCUH, NuTH and NHCFT only.
NYY: GREEN - approved for initiation in general practice if the necessary education/training* has been completed by the prescriber
* "Understanding chronic insomnia" [6 x 20-minute e-learning modules, provided by Idorsia Pharma Ltd.]

Prescribing in TEWV is supported as follows:
DTVF: "internal" use for exceptional cases only, in line with NICE criteria (below); approval via Single Application Form; prescribing cannot transfer to primary care .

NYY: TEWV clinicians may apply to initiate in line with NICE criteria via Single Application Form; prescribing can transfer to primary care but **only** to GPs who have completed the Idorsia training package (this should be confirmed in advance of initiating treatment); if GP not trained, prescribing must be retained by TEWV clinician.

TEWV prescribers must complete the Idorsia education/training linked above and indicate this has been done in their application to initiate treatment.

NICE Guidance (TA922)

- Daridorexant is recommended for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, only if:
  - Cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or
  - CBTi is not available or is unsuitable.
- The length of treatment should be as short as possible. Treatment with daridorexant should be assessed within 3 months of starting and should be stopped in people whose long-term insomnia has not responded adequately. If treatment is continued, assess whether it is still working at regular intervals.

Mode of action – orexin OX_1 and OX_2 receptor antagonist that blocks the action of orexin neuropeptides, thereby decreasing wakefulness

Dose – Usual/maximum dose **50 mg once per night**, taken orally in the evening within 30 minutes before going to bed; lower dose (25 mg once per night) may be clinically appropriate in some patients e.g. moderate hepatic impairment and patients taking moderate CYP3A4 inhibitors e.g., erythromycin, ciprofloxacin, cyclosporin. Absoprtion is unaffected by food but consumption of grapefruit or grapefruit juice in the evening should be avoided.

Older adults – Use with caution, especially in patients over75 years (limited data). No dose adjustment is required in patients over 65 years.

Monitoring and treatment duration - 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.

Deprescribing information - Treatment can be stopped without down-titration.

Available preparations – 25 mg and 50 mg tablets [£42 per pack of 30 (Oct 24 Drug Tariff)]

Contra-indications: Hypersensitivity to the active substance or to any of the excipients; Narcolepsy; Concomitant use with strong CYP3A4 inhibitors e.g., itraconazole, clarithromycin, ritonavir. Avoid in severe hepatic impairment.

Cautions:; use with other CNS-depressant agents including alcohol due to additive effects; patients with sleep paralysis, hallucinations and cataplexy-like symptoms; patients with depression – risk of worsening of depression and suicidal thoughts; patients with psychiatric co-morbidities; patients with compromised respiratory function including severe COPD, use in individuals with a history of abuse or addiction to alcohol or other substances

Interactions: (in addition to those already mentioned) – CYP3A4 inducers e.g., efavirenz may reduce daridorexant efficacy; caution if administered with sensitive CYP3A4 substrates with a narrow therapeutic index (e.g., high-dose simvastatin, tacrolimus) and P-gp substrates with a narrow therapeutic index (e.g., digoxin).

Most common adverse effects: headache, somnolence, dizziness, nausea & fatigue.

Title	PSS5 - Daridorexant	*To obtain a more accessible version of this document, please email: Tewv.pharmacyadmin@nhs.net*
Approved by D&T Committee	28th November 2024	
Review by	1st December 2027	