SUMMARY

daridorexant

QUVIVIQ 25 mg and 50 mg,

film-coated tablets

First assessment

Adopted by the Transparency Committee on 24 May 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion for reimbursement in “the treatment of adult patients with insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning”.

Role in the care pathway?

QUVIVIQ (daridorexant) 25 mg and 50 mg film-coated tablets are a second-line therapy in adults for the treatment of insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning.

The Committee highlights that in the event of failure of sleep hygiene measures, the use of non-medicinal treatments, such as cognitive behavioural therapy, should be favoured before initiating any medicinal treatment indicated in chronic insomnia.

Special recommendations

As regards the care pathway of patients, the Committee points out that:

- in the event of failure of sleep hygiene measures, the use of non-medicinal treatments, such as cognitive behavioural therapy, should be favoured before initiating any medicinal treatment indicated in chronic insomnia,
- an accurate and complete assessment of patients’ medical, psychological and social situation, and of their sleep habits, is necessary before prescribing any treatment indicated in chronic insomnia,

- no other hypnotic medicinal products are recommended in the treatment of chronic insomnia,
- the duration of treatment should be as short as possible. The appropriateness of continuing treatment should be assessed within 3 months and periodically thereafter.

Transparency Committee's conclusions

Clinical Benefit

- Sleep disturbances and the associated daytime repercussions can have harmful consequences on daily functioning and on the occurrence or exacerbation of physical or psychological conditions. Chronic insomnia can lead to personal and social complications with socio-professional repercussions.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is moderate.
- This is a second-line therapy in adults for the treatment of insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning.

Public health benefit

Considering:

- the disabling nature of chronic sleep disorders with an impact on daily life and long-term consequences,
- the high prevalence of these conditions,
- the partially met medical need,
- the partial response to the identified need:
  - the lack of any demonstrated impact on morbidity given the efficacy data on objective and subjective sleep variables after 12 weeks, and suggested after 12 months,
  - the absence of any specifically demonstrated impact on quality of life but nonetheless suggested by an impact on the IDSIQ "sleepiness" domain score (daytime functioning) demonstrated only at the 50-mg daridorexant dose (and not the 25-mg dose),
  - the lack of a demonstrated additional impact on the organisation of care in the absence of data,

QUVIVIQ (daridorexant) 25 mg and 50 mg film-coated tablets are unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of QUVIVIQ (daridorexant) 25 mg and 50 mg film-coated tablets is moderate in the MA indication.

The Committee issues a favourable opinion for inclusion of QUVIVIQ (daridorexant) 25 mg and 50 mg film-coated tablets in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 30%**

Clinical Added Value

Considering:

- demonstration of a superiority versus placebo after 12 weeks of treatment with daridorexant 25 mg (N=2 studies) and daridorexant 50 mg (N=1 study), with a low effect size on:
  - objective sleep variables, in the region of -5 to -25 minutes versus placebo depending on the doses, on wake after sleep onset (-10.3 to -22.8 minutes) and on latency to persistent sleep (-7.6 to -11.7 minutes),
  - the subjective sleep variable of total sleep time, in the region of 10 to 25 minutes versus placebo depending on the doses (+9.9 to +22.1 minutes),
- demonstration of a superiority versus placebo after 12 weeks of treatment with daridorexant only at the 50-mg dose on the IDSIQ “sleepiness” domain score (daytime functioning) in the region of -1.75 to -1.90 points out of 40,
- the acceptable safety profile of daridorexant at the two doses,
- the inadequately met medical need, with no other hypnotic medicinal products being recommended in the treatment of chronic insomnia,

but in view of:

- the absence of data enabling assessment of the superiority of daridorexant 25 mg and 50 mg compared to the non-medicinal therapies recommended as first-line treatment,
- the debatable clinical relevance of the result for the IDSIQ “sleepiness” domain score (daytime functioning) at the 50 mg dose of daridorexant only,
- the lack of evidence of maintenance of the long-term effect of daridorexant on objective and subjective sleep variables, given a lack of robust data,
- the limited nature of the safety data after 12 months, on a small number of randomised patients (around 60%),

the Committee deems that QUVIVIQ (daridorexant) 25 mg and 50 mg film-coated tablets provide a minor clinical added value (CAV IV) in adults for the treatment of insomnia characterised by symptoms present for at least 3 months and considerable impact on daytime functioning.