EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 February 2022
EMA/CHMP/72381/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Quviviq

daridorexant

On 24 February 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Quviviq, intended for the treatment of insomnia. The applicant for this medicinal product is Idorsia Pharmaceuticals Deutschland GmbH.

Quviviq will be available as 25 mg and 50 mg film-coated tablets. The active substance of Quviviq is daridorexant which works as dual orexin receptor antagonist.

The benefits of Quviviq are its ability to increase sleep induction, improve sleep maintenance and improve symptoms of daytime functioning. The most common side effects are headache and somnolence.

The full indication is:

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.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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