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Quviviq (*daridorexant*)

An overview of Quviviq and why it is authorised in the EU

What is Quviviq and what is it used for?

Quviviq is a medicine for treating adults with insomnia (difficulty sleeping) that has lasted for at least 3 months and has a considerable impact on how they function during the day.

Quviviq contains the active substance daridorexant.

How is Quviviq used?

The medicine can only be obtained with a prescription. It is available as tablets and the recommended dose is one 50-mg tablet in the evening not more than 30 minutes before going to bed. The dose could be one 25-mg tablet in the evening, if your doctor considers a lower dose as appropriate.

The effect of Quviviq may be delayed if taken with or soon after a meal. Your doctor may prescribe a lower dose if you have liver problems or take certain other medicines. Treatment should be kept as short as possible and reassessed by your doctor within 3 months.

For more information about using Quviviq, see the package leaflet or contact your doctor or pharmacist.

How does Quviviq work?

The active substance in Quviviq, daridorexant, is a dual orexin receptor antagonist (DORA). It works by blocking the action of orexin, a substance produced by the brain that promotes wakefulness. Quviviq does so by attaching to two types of receptors (targets) for orexin. This means that Quviviq helps people to fall asleep more quickly, to stay asleep for longer and to improve functioning during the day.

What benefits of Quviviq have been shown in studies?

Quviviq has been shown to be effective at increasing the amount of time adults with insomnia can sleep and improving functioning during the day based on two main studies. In one main study involving 930 patients those given 50 mg Quviviq over 3 months were able to reduce the time they spent awake each night by 29 minutes, on average, compared with a reduction of 11 minutes for those given a placebo (dummy treatment). Also, after 3 months of treatment, patients who took 50 mg

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Quviviq fell asleep around 35 minutes faster than before treatment, while those taking placebo fell asleep 23 minutes faster.

What are the risks associated with Quviviq?

The most common side effects with Quviviq (which may affect up to 1 in 10 people) are headache and somnolence (sleepiness). Most side effects are mild or moderate.

Quviviq must not be used in people who are hypersensitive (allergic) to any of the ingredients, in people with narcolepsy (a sleep disorder that causes a person to fall asleep suddenly and unexpectedly), or in people who use 'strong CYP3A4 inhibitors' (a group of medicines).

For the full list of side effects and restrictions of Quviviq, see the package leaflet.

Why is Quviviq authorised in the EU?

Two main studies showed that Quviviq is effective at increasing the amount of time patients with insomnia can sleep and improving functioning during the day. The side effects are considered manageable. The European Medicines Agency therefore decided that Quviviq's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Quviviq?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Quviviq have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Quviviq are continuously monitored. Suspected side effects reported with Quviviq are carefully evaluated and any necessary action taken to protect patients.

Other information about Quviviq

Quviviq received a marketing authorisation valid throughout the EU on 29 April 2022.

Further information on Quviviq can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/quviviq.

This overview was last updated in 04-2022.