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QUVIVIQ® (Active substance: daridorexant)

First authorisation in Switzerland: 1 December 2022

Medicinal product (film-coated tablets) for the treatment of adults with insomnia that has lasted for at least 3 months.

About the medicinal product

The medicinal product QUVIVIQ, containing the active substance daridorexant, is used to treat adults who have had insomnia (difficulty sleeping) for at least 3 months and whose daily life is substantially impacted by the associated symptoms.

Insomnia is a widespread condition and can impair patients' ability to function on a daily basis. Furthermore, the symptoms of insomnia can negatively impact their health.

There are 3 characteristic symptoms of insomnia: Difficulty with sleep onset, difficulty with sleep maintenance, and unrefreshing sleep that negatively affects patients' daily activity, despite adequate opportunities and a good environment for sleep.

Mode of action

Two molecules, orexin A and orexin B, play an important role in insomnia by promoting wakefulness. Daridorexant, the active substance of QUVIVIQ, is an orexin receptor antagonist.[1] Daridorexant intervenes in the orexin system, preventing the orexin molecules responsible for wakefulness from binding to their receptors. This mode of action is conducive to sleep by inhibiting the orexin A and B signalling that promotes wakefulness.

Indication

QUVIVIQ, containing the active substance daridorexant, is a prescription-only medicine available as film-coated tablets containing 25 mg or 50 mg of active substance in packs of 10 or 30 film-coated tablets.

[1] Receptor antagonist: Receptors are very specific docking sites. Receptors exist for numerous substances. As soon as a specific substance binds to its receptor, it triggers a reaction in the cell. An antagonist blocks a receptor, thereby preventing the substance from binding to that receptor.

The recommended daily dose for adults is 50 mg, to be taken in the evening, 30 minutes before going to bed. Depending on patients' individual situation, doctors may also prescribe a lower dose of 25 mg per night. QUVIVIQ can be taken with or without food. However, patients should avoid eating grapefruit or drinking grapefruit juice during the evening since this could impair the action of QUVIVIQ.

Treatment with QUVIVIQ should be kept as short as possible. Doctors should reassess within 3 months and subsequently whether further treatment is indicated.

Efficacy

The efficacy of QUVIVIQ, containing the active substance daridorexant, was evaluated in adult insomnia patients in 2 trials involving a total of 1,854 participants.

For a period of 3 months, participants took either QUVIVIQ or a dummy treatment (placebo) before going to bed. After the 3-month treatment period had ended, the efficacy of daridorexant was investigated in a total of 576 participants for a further period of at least 6 months and in 331 participants for at least 12 months as part of an additional long-term trial.

A sleep laboratory monitored the change in sleep onset time and wakefulness after sleep onset. In addition, participants documented subjective total sleep time and daytime functioning.

The trials demonstrated that sleep onset time and wakefulness after sleep onset improved after just 1 week in patients who took QUVIVIQ, containing the active substance daridorexant, compared with those who took the dummy medication. Improved total sleep time, sleep quality, and daily activity were observed in trial participants.

Precautions, undesirable effects & risks

QUVIVIQ must not be used in patients who are hypersensitive to the active substance or any of the excipients, in patients with narcolepsy (a sleep disorder that causes a person to fall asleep suddenly and unexpectedly), or in patients who are taking certain medicinal products (e.g. antibiotics or medicinal products for the treatment of fungal infections or HIV).

The commonest undesirable effects are headache (6%), sleepiness (2%), dizziness, and nausea (≥ 1%).

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

QUVIVIQ can reduce sleep onset time and wakefulness after sleep onset and improve sleep quality in adult patients who have been suffering from insomnia for at least 3 months and whose daily life is substantially impacted by the associated symptoms. Since QUVIVIQ has a different mode of action from conventional sleeping aids, its potential for misuse is low.

Taking all the risks and precautions into account, and based on the available data, the benefits of QUVIVIQ outweigh the risks.

Swissmedic has therefore authorised the medicine QUVIVIQ, with the active substance daridorexant, for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals QUVIVIQ

Information for patients (package leaflet):
Information for patients QUVIVIQ

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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