

Daridorexant (Quviviq®) for adult patients: Frequently Asked Questions (FAQs)

Daridorexant (Quviviq®)

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This document contains electronic links and web addresses to supporting information. If you would like paper copies of these documents, please contact HWE ICB. Our contact details are provided below:

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1. **What is daridorexant (Quviviq®)?**

Daridorexant (Quviviq®) is used in the treatment of insomnia in adults. It belongs to a group of medicines called orexin receptor antagonist. Orexin is a substance produced by the brain which helps keep you awake. Daridorexant (Quviviq®) blocks the action of orexin to enable you to fall asleep faster and stay asleep for longer. This in turn should improve your ability to function normally in the day.

Who is eligible for Daridorexant (Quviviq®) on the NHS?

Daridorexant (Quviviq®) has been recommended by NICE for treating insomnia in adults who meet the following strict criteria:

- a) Have symptoms of insomnia lasting for **three nights or more per week** for at least **three months and**
- b) Whose **daytime functioning** is considerably affected **and**
- c) **Cognitive behavioural therapy for insomnia** has been tried and not worked or is unavailable/unsuitable

2. **How do I get Daridorexant (Quviviq®) in Hertfordshire and West Essex?**

Only patients who meet the above criteria will be eligible for treatment. Sleep hygiene measures (good sleeping habits), cognitive behavioural therapy for insomnia (when available), and looking into any other causes of your insomnia should have been tried first.

Some GPs may require further support and training to diagnose long term insomnia. This is because diagnosing this is difficult, and this has been acknowledged by NICE.

Daridorexant (Quviviq®) is a new approved drug, and your GP may be unfamiliar and lack experience in using this treatment. GPs will only prescribe this treatment option if they have a clear understanding of your sleep difficulties and are satisfied that the medicine will be suitable for you.

If you are eligible for daridorexant (Quviviq®), and after a discussion with your GP there is agreement that this is a suitable treatment option then your GP can prescribe this for you. If your GP considers daridorexant (Quviviq®) would not be a suitable treatment option for your insomnia, this will be explained to you and other treatment options can be discussed.

Daridorexant (Quviviq®) is not suitable for children and adolescents under the age of 18 years.

3. **What are the risks of daridorexant (Quviviq®) treatment?**

- Daridorexant (Quviviq®) is a new drug and clinical trial data is only available for up to 12 months of treatment. Therefore, the long term effects of this drug are still unknown.
- Talk to your doctor or pharmacist before taking daridorexant (Quviviq®) if you have a history of falling and are older than 65 years (because there is generally a higher risk of falling in patients older than 65 years).
- Drinking alcohol with daridorexant (Quviviq®) can increase the risk of impaired balance and coordination.
- A period of approximately 9 hours is recommended between taking daridorexant (Quviviq®) and driving or using machines. Be cautious about driving or using machines in the morning after taking daridorexant (Quviviq®). Do not engage in potentially hazardous activities if you are not sure you are fully alert, especially in the first few days of treatment.

4. **What cautions and precautions do I need to take when considering treatment with daridorexant (Quviviq®)?**

You should not take daridorexant (Quviviq®) if:

- you are allergic to daridorexant (Quviviq®) or any of the other ingredients in this medicine.
- if you have narcolepsy, a condition that causes you to suddenly and unexpectedly fall asleep at any time.

- if you are taking medicines which may increase the level of daridorexant (Quviviq®) in your blood such as: -
 - oral medicines to treat fungal infections such as ketoconazole, posaconazole, voriconazole, itraconazole.
 - certain medicines to treat bacterial infections such as the antibiotics clarithromycin, josamycin, telithromycin, troleandomycin.
 - certain medicines to treat HIV infection such as ritonavir, elvetegravir, indinavir, saquinavir, telaprevir, danoprevir, lopinavir, nelfinavir, boceprevir.
 - certain medicines to treat cancer such as ceritinib, idelalisib, ribociclib, tucatinib.

Talk to your doctor or pharmacist before taking daridorexant (Quviviq®) if you:

- have depression or have or ever had suicidal thoughts
- have a psychiatric disorder
- currently take medicinal products that affect your brain such as treatments for anxiety or depression
- have regularly taken drugs (except as medicines) or been addicted to drugs or alcohol
- have liver problems: depending on their severity, daridorexant (Quviviq®) may not be recommended, or a lower dose might be required
- have breathing difficulties (such as severe obstructive sleep apnoea or severe chronic obstructive pulmonary disease)
- have a history of falling and are older than 65 (because there is generally a higher risk of falling in patients > 65).

Your doctor will consider if this is an appropriate treatment and/or may want to monitor how the medicine affects you.

5. What side effects could I experience with daridorexant (Quviviq®)?

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Common side effects (may affect up to 1 in 10 people):

- headache - excessive sleepiness - dizziness - tiredness - feeling sick (nausea)

Uncommon side effects (may affect up to 1 in 100 people):

- temporary inability to move or talk (sleep paralysis) for up to several minutes while you are going to sleep or waking up
 - seeing or hearing vivid or disturbing things that are not real (hallucinations).

Tell your doctor if you get any of the following side effects while taking daridorexant (Quviviq®):

- sleep paralysis; hallucinations; if you have depression and you experience a worsening or have thoughts of harming yourself, call your doctor straight away.

6. How do I take daridorexant (Quviviq®)?

Daridorexant is an oral tablet which is taken once each night in the 30 minutes before going to bed. This can be taken with or without food but may take longer to work if taken with or after a large meal. The usual dose is 50mg each night. A lower dose, 25mg may be given if you have liver problems or take certain other medicines.

7. How long can I take daridorexant (Quviviq®) for my insomnia and when will my treatment be reviewed?

Daridorexant (Quviviq®) should be taken for as short a time as possible and your GP should assess continuing treatment within 3 months of starting treatment and regularly after that. As this is a new drug information on its longer-term continuous use is currently only available for up to a 12 month period.

Treatment will be stopped if your long-term insomnia has not responded sufficiently. This will ensure you are not taking a medicine which is not working for you.

It is important to note that sleep hygiene measures and behavioural changes for people with insomnia are essential to maximise the treatment effect for daridorexant (Quviviq®). Therefore, your GP may ask for a sleep diary and more details about your insomnia to ensure you are doing as much as possible to help improve your sleep before agreeing to continue treatment.

8. What happens if I miss a dose of daridorexant (Quviviq®)?

If you forget to take daridorexant (Quviviq®) at bedtime, then you should not take it later during the night, otherwise you may feel drowsy in the morning. Also, do not take a double dose if you have forgotten to take a tablet.

9. Can I become addicted/dependent on daridorexant (Quviviq®)?

In clinical studies there was no evidence to show that daridorexant (Quviviq®) can lead to physical dependence on the drug, or that when stopping the drug withdrawal symptoms can occur. However, if you have a history of abuse or addiction to alcohol or other substances, you may be at an increased risk of abuse of daridorexant (Quviviq®).

How do I stop treatment with daridorexant (Quviviq®)?

You can stop taking daridorexant (Quviviq®) without the need to gradually reduce the dose, and without harmful effects.

10. Where would I be able to find more information on daridorexant (Quviviq®)

A copy of the daridorexant (Quviviq®) patient information leaflet is available at <https://www.medicines.org.uk/emc/files/pil.15359.pdf>

11. What other treatment options are available for insomnia?

You may be referred to a sleep clinic or neurologist if your GP considers that you may have another sleep disorder or if your long-term insomnia has not responded to treatment options recommended through your GP practice.

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