

**MEDICATION GUIDE**  
**QUVIVIQ® (cue-VIH-vick)**  
**(daridorexant)**  
**tablets, for oral use, CIV**

**What is the most important information I should know about QUVIVIQ?**

**QUVIVIQ may cause serious side effects, including:**

- **Decreased awareness and alertness.** The morning after you take QUVIVIQ, your ability to drive safely and think clearly may be decreased. You may also have sleepiness during the day. Sleepiness may increase your risk for falls.
  - Do not take more QUVIVIQ than prescribed.
  - Do not take QUVIVIQ unless you are able to stay in bed for a full night (at least 7 hours) before you must be active again.
  - Take QUVIVIQ in the evening within 30 minutes before going to bed.

See **“What are the possible side effects of QUVIVIQ?”** for more information about side effects.

**What is QUVIVIQ?**

- QUVIVIQ is a prescription medicine for adults who have trouble falling asleep or staying asleep (insomnia).
- It is not known if QUVIVIQ is safe and effective for use in children.

QUVIVIQ is a federally controlled substance (CIV) because it can be abused or lead to dependence. Keep QUVIVIQ in a safe place to prevent misuse and abuse. Selling or giving away QUVIVIQ may harm others and is against the law.

**Who should not take QUVIVIQ?**

**Do not take QUVIVIQ:**

- **If you fall asleep often at unexpected times (narcolepsy).**
- **If you are allergic to daridorexant, or any ingredients in QUVIVIQ.** See the end of this Medication Guide for a complete list of ingredients in QUVIVIQ.

**Before taking QUVIVIQ, tell your healthcare provider about all of your medical conditions, including if you:**

- have a history of depression, mental illness, or suicidal thoughts or actions
- have a history of drug or alcohol abuse or addiction
- have a history of a sudden onset of muscle weakness (cataplexy)
- have a history of daytime sleepiness
- have lung or breathing problems, including sleep apnea
- have liver problems
- are pregnant or plan to become pregnant. It is not known if QUVIVIQ can harm your unborn baby.
  - **Pregnancy Registry:** There is a pregnancy registry for women who are exposed to QUVIVIQ during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. For more information or to participate in the registry, call 1-833-400-9611. Talk with your healthcare provider about the risk to your unborn baby if you take QUVIVIQ during pregnancy.
- are breastfeeding or plan to breastfeed. QUVIVIQ passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with QUVIVIQ.

**Tell your healthcare provider about all of the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking QUVIVIQ with certain medicines can cause serious side effects. QUVIVIQ may affect the way other medicines work and other medicines may affect the way QUVIVIQ works.

**Do not take QUVIVIQ with other medicines that can make you sleepy unless your healthcare provider tells you to.**

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**How should I take QUVIVIQ?**

- Take QUVIVIQ exactly as your healthcare provider tells you to take it.
- Do not change your dose of QUVIVIQ without first talking to your healthcare provider.
- **Take QUVIVIQ one time each night**, within 30 minutes before going to bed.
- Only take QUVIVIQ when you can stay in bed for a full night (at least 7 hours).

- QUVIVIQ may take longer to work if you take it with or right after a meal.
- Call your healthcare provider if your insomnia (sleep problem) worsens or is not improved within 7 to 10 days. This may mean that there is another condition causing your sleep problem.
- If you take too much QUVIVIQ, call your healthcare provider, or contact your Poison Help Line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

#### What should I avoid while taking QUVIVIQ?

- **Do not** drink alcohol while taking QUVIVIQ. It can increase the effects of alcohol, which can be dangerous.
- You may still feel drowsy the next day after taking QUVIVIQ.
  - **Do not** drive, operate heavy machinery, do anything dangerous, or do other activities that require clear thinking if you have taken QUVIVIQ as prescribed but do not feel fully awake, you have taken QUVIVIQ and have had less than a full night of sleep (at least 7 hours), or if you have taken more QUVIVIQ than prescribed by your healthcare provider.

#### What are the possible side effects of QUVIVIQ?

##### QUVIVIQ may cause serious side effects, including:

- See [“What is the most important information I should know about QUVIVIQ?”](#)
- **Worsening depression and suicidal thoughts.** Call your healthcare provider right away if you have any worsening depression or thoughts of suicide or dying.
- **Temporary inability to move or talk (sleep paralysis)** for up to several minutes, or hallucinations while you are going to sleep or waking up.
- **Temporary weakness in your legs that can happen during the day or at night.**
- **Complex sleep behaviors** such as sleepwalking, sleep driving, preparing and eating food, making phone calls, having sex, or doing other activities while not fully awake that you may not remember the next morning. Stop taking QUVIVIQ and call your healthcare provider right away if you experience a complex sleep behavior.

**The most common side effects of QUVIVIQ include** headache and sleepiness or tiredness.

These are not all of the possible side effects of QUVIVIQ.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### How should I store QUVIVIQ?

- Store QUVIVIQ at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep QUVIVIQ and all medicines out of the reach of children.**

#### General information about the safe and effective use of QUVIVIQ.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use QUVIVIQ for a condition for which it was not prescribed. Do not give QUVIVIQ to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about QUVIVIQ that is written for health professionals.

#### What are the ingredients in QUVIVIQ?

**Active ingredient:** daridorexant hydrochloride

**Inactive ingredients:** croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, povidone, and silicon dioxide. The tablet film coating contains: glycerin, hypromellose, iron oxide black, iron oxide red, microcrystalline cellulose, talc, titanium dioxide, and, in the 50 mg tablet only, iron oxide yellow.

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For more information go to [QUVIVIQ.com](http://QUVIVIQ.com) or call 1-833-400-9611.