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# DARIDOREXANT (Quviviq) Fact Sheet

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## Bottom Line:

Daridorexant is the third agent in the class of orexin receptor antagonists. Like the other agents in its class, it is no more effective than benzos or Z-drugs, and it has a similar abuse liability. We're concerned that next-day impairment is a potential side effect at the higher dose, particularly since sleepless patients may decide on their own to take even higher doses. It's not a first-line hypnotic.

## FDA Indications:

**Insomnia** (sleep onset and sleep maintenance).

## Dosage Forms:

**Tablets:** 25 mg, 50 mg.

## Dosage Guidance:

Start 25 mg QHS, 30 minutes before bedtime and at least seven hours before planned awakening time. If tolerated but not effective, may increase to max 50 mg QHS. For more rapid onset, patients should wait at least an hour after a meal before taking it. Avoid administering within an hour of a high-fat meal (delays therapeutic effect by about 1.5 hours).

**Monitoring:** No routine monitoring recommended unless clinical picture warrants.

**Cost:** \$\$\$\$\$

## Side Effects:

- Most common: Somnolence, headache, fatigue.
- Serious but rare: Impaired alertness and motor coordination, including impaired driving; worsening depression or suicidal ideation; sleep paralysis (inability to speak or move for up to a few minutes during the sleep-wake transition), hypnagogic/hypnopompic hallucinations (including vivid and disturbing perceptions), and cataplexy-like symptoms (leg weakness for seconds up to a few minutes both in the nighttime and the daytime) reported, especially at higher doses.
- Pregnancy/breastfeeding: Not enough data to recommend.

## Mechanism, Pharmacokinetics, and Drug Interactions:

- "DORA" or dual orexin (OX1 and OX2) receptor antagonist.
- Metabolized primarily through CYP3A4; t<sub>1/2</sub>: 8 hours.
- Caution with CYP3A4 inhibitors and inducers; daridorexant dose adjustment recommended. Caution with alcohol and other CNS depressants.

## Clinical Pearls:

- Daridorexant, like other DORAs, has a unique mechanism of action. Unlike other hypnotics, it does not act by stimulating GABA or melatonin receptors or by blocking histamine. Instead, daridorexant blocks orexin receptors (orexins are neurotransmitters that promote wakefulness).
- Schedule IV controlled substance. Data in recreational drug users found they "liked" daridorexant more than placebo and as much as zolpidem and suvorexant.
- Daridorexant is contraindicated in patients with narcolepsy.
- Risk of next-day impairment increases with dose; caution patients taking 50 mg against next-day driving and other activities requiring mental alertness.
- In studies of daridorexant, patients over the age of 65 had a higher likelihood of somnolence and fatigue.
- Of the three DORA agents, daridorexant has the shortest half-life, contributing to potentially less impairment of daytime functioning. The manufacturer has petitioned the FDA for this distinction, but that decision remains pending.
- Just as with use of other hypnotics, monitor and assess patients for suicidality, especially those with depression.
- The US Department of Defense is currently enrolling military service members and veterans with PTSD in a study comparing several medications, including daridorexant.

## Fun Fact:

Quviviq's manufacturer has been marketing this drug heavily, including television ads featuring celebrities like actor Taye Diggs and Olympic skier Lindsey Vonn.