QUVIVIQ
(daridorexant) IV 25mg, 50mg tablets

Advances in the Treatment of Insomnia

A Product Showcase by Idorsia Pharmaceuticals US, Inc.

Led by:

Sachin Mehta, MD
Medical Director
Springfield Psychological
Blue Bell, PA

The event is being held during the
American Psychiatric Association Annual Meeting
at the following date and location:

Tuesday, May 24
1:00 PM – 2:00 PM
New Orleans Morial Convention Center
Exhibit Halls G-J, First Floor

Come learn more about QUVIVIQ™ (daridorexant) at Booth 2919.

INDICATION

QUVIVIQ (daridorexant) is indicated for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

QUVIVIQ is contraindicated in patients with narcolepsy.

Please see additional important safety information on the following page and full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Central Nervous System (CNS) Depressant Effects and Daytime Impairment

QUVIVIQ can impair daytime wakefulness. CNS depressant effects may persist in some patients up to several days after discontinuing QUVIVIQ. Advise patients about the potential for next-day somnolence.

Driving ability was impaired in some subjects taking QUVIVIQ 50 mg. Risk of daytime impairment is increased if QUVIVIQ is taken with less than a full night of sleep or at a higher than recommended dose. If taken in these circumstances, caution patients against driving or other activities requiring complete mental alertness.

Use with other CNS depressants increases the risk of CNS depression, which can cause daytime impairment. Dosage adjustments of QUVIVIQ and CNS depressants may be necessary when administered together. Use with other insomnia drugs is not recommended. Advise patients not to consume alcohol in combination with QUVIVIQ.

Worsening of Depression/Suicidal Ideation

Patients with psychiatric disorders including insomnia are at increased risk of suicide. In primarily depressed patients treated with hypnotics, worsening of depression, suicidal thoughts and actions (including completed suicides) have been reported. Administer with caution in patients exhibiting symptoms of depression. Monitoring suicide risk and protective measures may be required.

Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations, and Cataplexy-Like Symptoms

Sleep paralysis, an inability to move or speak for up to several minutes during sleep-wake transitions, and hypnagogic/hypnopompic hallucinations, including vivid and disturbing perceptions, can occur with QUVIVIQ. Explain these events to patients.

Symptoms similar to mild cataplexy have been reported with orexin receptor antagonists and can include periods of leg weakness lasting from seconds to a few minutes, can occur at night or during the day, and may not be associated with a triggering event (e.g., laughter or surprise).

Complex Sleep Behaviors

Complex sleep behaviors, including sleep-walking, sleep-driving, and engaging in activities while not fully awake (e.g., preparing and eating food, making phone calls, having sex), have been reported to occur with the use of hypnotics, including orexin receptor antagonists, such as QUVIVIQ. These events can occur in hypnotic-naïve as well as in hypnotic-experienced persons. Patients usually do not remember these events. Complex sleep behaviors may occur following the first or any subsequent use of hypnotics, with or without the concomitant use of alcohol and other CNS depressants. Discontinue QUVIVIQ immediately if a patient experiences a complex sleep behavior.

Patients with Compromised Respiratory Function

The effects of QUVIVIQ on respiratory function should be considered for patients with compromised respiratory function. QUVIVIQ has not been studied in patients with moderate obstructive sleep apnea (OSA) requiring CPAP, severe OSA or severe chronic obstructive pulmonary disease (COPD).

Need to Evaluate for Comorbid Diagnoses

Treatment of insomnia should be initiated only after careful evaluation of the patient. Re-evaluate for comorbid conditions if insomnia fails to remit after 7 to 10 days of treatment. Worsening insomnia or new cognitive or behavioral abnormalities may be the result of an underlying psychiatric or medical disorder and can emerge during treatment with sleep-promoting drugs such as QUVIVIQ.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions (reported in ≥ 5% of patients treated with QUVIVIQ and at an incidence ≥ placebo) were headache and somnolence or fatigue.

DRUG INTERACTIONS

- **CYP3A4 Inhibitors:** The recommended dose of QUVIVIQ is 25 mg when used with a moderate CYP3A4 inhibitor. Concomitant use of QUVIVIQ with a strong inhibitor of CYP3A4 is not recommended.
- **CYP3A4 Inducers:** Concomitant use of QUVIVIQ with a strong or moderate inducer of CYP3A4 is not recommended.

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation

There are no available data on QUVIVIQ use in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to QUVIVIQ during pregnancy. Pregnant women exposed to QUVIVIQ and healthcare providers are encouraged to call Idorsia Pharmaceuticals at 1-833-400-9611.

There are no data on the presence of daridorexant in human milk, the effects on the breastfed infant, or the effects on milk production. Monitor infants exposed to QUVIVIQ through breastmilk for excessive sedation.

Geriatric Use

Because QUVIVIQ can increase somnolence and drowsiness, patients, particularly the elderly, are at higher risk of falls. No dosage adjustment is required in patients over the age of 65 years.

Hepatic Impairment

QUVIVIQ is not recommended in patients with severe hepatic impairment. Reduce the dose in patients with moderate hepatic impairment.

DRUG ABUSE AND DEPENDENCE

- QUVIVIQ is a Schedule IV controlled substance.
- Because individuals with a history of abuse or addiction to alcohol or other drugs may be at increased risk for abuse and addiction to QUVIVIQ, follow such patients carefully.

Please see additional important safety information on the previous page and full Prescribing Information.

This is an informational event provided by Idorsia Pharmaceuticals, US. Participants cannot claim CME credit for attending this informational event and participation may be subject to reporting under the Sunshine Act. The Industry Product Showcase contract and the views expressed therein are those of Idorsia Pharmaceuticals, US and not of APA.

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