A novel approach in pediatric ADHD (ages 6 to 17)...

ONCE-DAILY
Qelbree™
viloxazine
extended-release capsules
100 mg 150 mg 200 mg

PRODUCT THEATER:

Join us to discuss "Qelbree: the only NCE approved for the treatment of ADHD in over a decade"[1,2]

Facilitators:

Frank Lopez, MD
Neurodevelopmental Pediatrician
Pediatrics Neurology PA
Pediatric Epilepsy and Research Center
Assistant Director of Clinical Research
Winter Park, Florida

Andrew J. Cutler, MD
Clinical Associate Professor of Psychiatry
SUNY Upstate Medical University
Chief Medical Officer
Neuroscience Education Institute
Lakewood Ranch, Florida

Date: Saturday, October 9, 2021
Time: 12:00 PM–1:00 PM CDT
Location: Join our Zoom Meeting at:
https://zoom.us/j/92473922397

Supernus proudly supports the American Academy of Pediatrics (AAP).

Abbreviations: NCE, new chemical entity.

The presentation for this Product Theater is not designated for CME credit. This presentation is neither sponsored nor endorsed by the American Academy of Pediatrics.

INDICATION

Qelbree is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in pediatric patients ages 6 to 17.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

In clinical studies, higher rates of suicidal thoughts and behaviors were reported in pediatric patients with ADHD treated with Qelbree than in patients treated with placebo. Closely monitor all Qelbree-treated patients for clinical worsening and for emergence of suicidal thoughts and behaviors.

Please see full Prescribing Information and additional Important Safety Information, on back.

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CONTRAINDICATIONS

- Concomitant administration of a monoamine oxidase inhibitor (MAOI), or dosing within 14 days after discontinuing an MAOI, because of an increased risk of hypertensive crisis
- Concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range

WARNINGS & PRECAUTIONS

- *Suicidal Thoughts and Behaviors*: Closely monitor all Qelbree-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy, and at times of dosage changes
- *Heart rate*, *blood pressure increases*: Qelbree can cause an increase in diastolic blood pressure and heart rate. Assess these measures prior to starting therapy, following increases in dosage, and periodically during therapy
- *Activation of mania or hypomania*: Noradrenergic drugs may induce a manic or mixed episode in patients with bipolar disorder. Prior to initiating treatment with Qelbree, screen patients to determine if they are at risk for bipolar disorder. Screening should include a detailed psychiatric history, including a personal or family history of suicide, bipolar disorder, and depression
- *Somnolence and fatigue*: Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, due to potential somnolence (including sedation or lethargy) and fatigue, until they know how they will be affected by Qelbree

ADVERSE REACTIONS

The most common adverse reactions (≥5% and at least twice the rate of placebo for any dose) were somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability.

DOSING SAFETY INFORMATION

- Swallow Qelbree capsules whole or sprinkle entire contents on a teaspoonful of applesauce and consume all within 2 hours, without regard to meals. Do not cut, crush, or chew the capsules
- Severe renal impairment: Initiate Qelbree at 100 mg once daily and increase by 50 mg to 100 mg at weekly intervals to a maximum recommended dosage of 200 mg once daily
- Qelbree is a strong CYP1A2 inhibitor. Coadministration with moderately sensitive CYP1A2 substrates (eg, clozapine and pirfenidone) is not recommended. If coadministered, dose reduction may be warranted
- Qelbree is a weak inhibitor of CYP2D6 and CYP3A4, which increases exposure of those substrates (eg, dextromethorphan and alfentanil) when coadministered with Qelbree. Monitor patients for adverse reactions and adjust dosages of substrates as clinically indicated

  –*For a more complete list of drug-to-drug interactions, including clinical effects and examples, please see table 2 in section 7 of the full Prescribing Information*

PREGNANCY & LACTATION

- Qelbree may cause maternal harm. It is not known if Qelbree passes into breastmilk or if Qelbree has an effect on the breastfed infant. Discontinue Qelbree if the risks of therapy during pregnancy outweigh the benefits

Please see full Prescribing Information, including Boxed Warning.

REFERENCE: 1. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc. **2.** Vyvanse [package insert]. Lexington, MA: Shire US.