

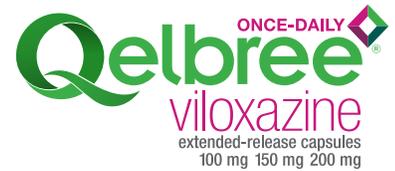
**INDICATION**

Qelbree is indicated for the treatment of ADHD in adults and pediatric patients 6 years and older.

**IMPORTANT SAFETY INFORMATION**

**WARNING: SUICIDAL THOUGHTS AND BEHAVIORS**

In clinical studies, higher rates of suicidal thoughts and behaviors were reported in 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 Important Safety Information on page 2.

**STRESSED OUT STACY**



Patient portrayal.

Do you **RE**cognize stressed out Stacy?

- ▶ **RE**peatedly makes careless mistakes<sup>1</sup>
- ▶ **RE**lentlessly daydreams and fails to listen<sup>1</sup>
- ▶ **RE**veals her inability to focus, concentrate, or get things done<sup>1</sup>
- ▶ **RE**gularly has trouble managing time and staying organized<sup>1</sup>
- ▶ **RE**routes herself most mornings while looking for misplaced items<sup>1</sup>
- ▶ **RE**adily avoids doing most tasks until the last minute<sup>1</sup>
- ▶ **RE**grets that she frequently turns in assignments late<sup>1</sup>

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Need to help **RE**duce the distract in her act?

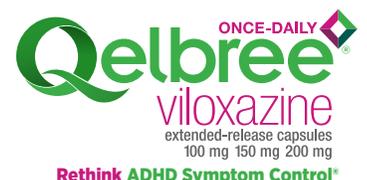
It may be time to stress the importance of **RE**thinking ADHD symptom control with nonstimulant **Qelbree**<sup>2</sup>

- ▶ First novel, nonstimulant approach in ADHD in over a decade<sup>2,3</sup>  
–First nonstimulant approved for adult ADHD in 20 years<sup>2</sup>
- ▶ Proven efficacy in treating ADHD: inattention and hyperactivity/impulsivity symptom score reductions observed early in treatment<sup>\*2,4</sup>
- ▶ Proven safety and tolerability, with no evidence of abuse potential<sup>2,5,6</sup>
- ▶ Once-daily, rapid- and extended-release, sprinkleable capsules for full-day exposure<sup>2,4</sup>

\*Qelbree was studied in 4 clinical trials. In one study of children 6 to 11 years of age, ADHD symptom score reductions were statistically significant for the 100 mg and 200 mg doses, beginning at week 1. In the study of teens 12 to 17 years of age, ADHD symptom score reductions were statistically significant for the 400 mg dose, beginning at week 2. In the flexible-dose study of adults 18 to 65 years of age, ADHD symptom score reductions were statistically significant in patients taking Qelbree, beginning at week 2.

**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



Abbreviation: ADHD, attention-deficit/hyperactivity disorder; HCP, healthcare professional.

## INDICATION

Qelbree® (viloxazine extended-release capsules) is indicated for the treatment of ADHD in adults and pediatric patients 6 years and older.

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## CONTRAINDICATIONS

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## 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 ( $\geq 5\%$  and at least twice the rate of placebo for any dose) in patients 6 to 17 years were somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability, and in adults, insomnia, headache, somnolence, fatigue, nausea, decreased appetite, dry mouth, and constipation.

## PREGNANCY

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Qelbree during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Psychiatric Medications at 1-866-961-2388 or by visiting [www.womensmentalhealth.org/preg](http://www.womensmentalhealth.org/preg).

**REFERENCES:** 1. Adler L, Spencer T, Biederman MD. Adult ADHD Investigator Symptom Rating Scale (AISRS). Massachusetts General Hospital and New York University School of Medicine; 2010. 2. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc. 3. Food and Drug Administration. Novel drug approvals for 2021. May 13, 2022. Accessed January 9, 2023. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021>. 4. Data on file, Supernus Pharmaceuticals. 5. Yanagita T, Wakasa Y, Kiyohara H. Drug dependence potential of viloxazine hydrochloride tested in rhesus monkeys. *Pharmacol Biochem Behav.* 1980;12:155-161. 6. Food and Drug Administration. Table of Prescription Stimulant Label Changes. May 10, 2023. Accessed July 13, 2023. <https://www.fda.gov/media/168050/download>.

Please see full **Prescribing Information**, including **Boxed Warning**.



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