

**ATTENTION: LABEL UPDATE—
including revisions to sections 12.2 and 8.2
of the Qelbree Prescribing Information!¹**

Qelbree pharmacodynamics go beyond norepinephrine reuptake inhibition¹

INDICATION

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

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

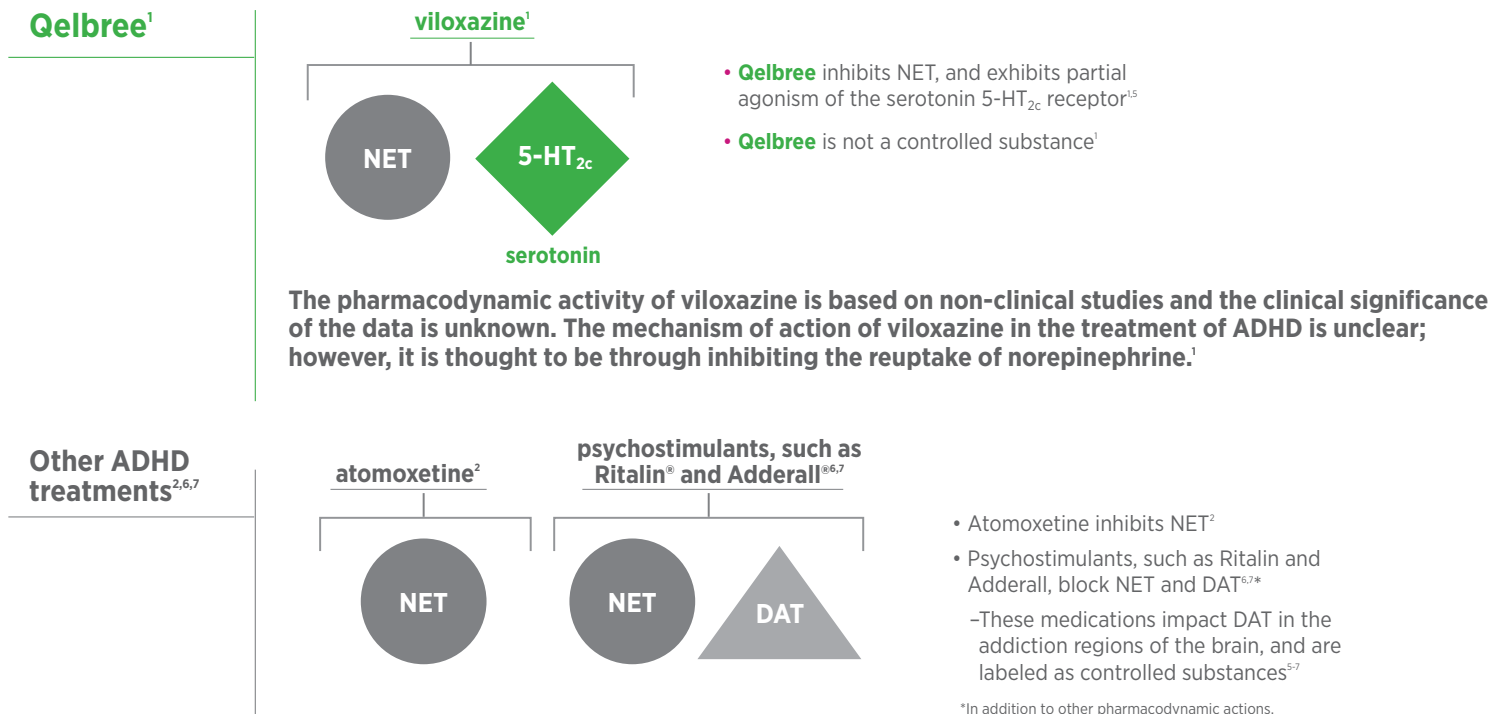
In clinical studies, higher rates of suicidal thoughts and behaviors were reported in patients with ADHD treated with Qelbree than in patients treated with placebo. Closely monitor all Qelbree-treated patients for clinical worsening and for emergence of suicidal thoughts and behaviors.

Abbreviation: ADHD, attention-deficit/hyperactivity disorder.

Please see full [Important Safety Information](#) on page 3.

Qelbree[®] ONCE-DAILY
viloxazine
extended-release capsules
100 mg 150 mg 200 mg

Qelbree is the first and only ADHD nonstimulant with a multimodal pharmacodynamic profile¹⁻⁴



Qelbree is the first ADHD treatment to receive labeling approval following the 2019 FDA guidance on clinical lactation studies¹

- Data from the study involving 15 healthy lactating women show the transference of viloxazine into breast milk is low¹

There are no data on the effects of viloxazine on the breastfed infant or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Qelbree and any potential adverse effects on the breastfed child from Qelbree or from the underlying maternal condition.¹

Abbreviations: DAT, dopamine transporter; FDA, Food and Drug Administration; NET, norepinephrine transporter.

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

Please see full [Important Safety Information](#) on page 3.



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.

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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.

REFERENCES: 1. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc. 2. Strattera [package insert]. Indianapolis, IN: Lilly USA, LLC. 3. Kapvay [package insert]. Atlanta, GA: Shionogi Pharma, Inc. 4. Intuniv [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A. 5. Stahl SM. Stahl's *Essential Psychopharmacology: Neuroscientific Basis and Practical Applications*. 5th ed. Cambridge University Press; 2021. 6. Ritalin [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. 7. Adderall [prescribing information]. Horsham, PA: Teva Pharmaceuticals USA.

Please see full [Prescribing Information](#), including **Boxed Warning**.



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