DATA UPDATE

ATTENTION: LABEL UPDATE—
including revisions to Section 12.2 of the Qelbree Prescribing Information[1]

This article is sponsored by Supernus Pharmaceuticals

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 3.

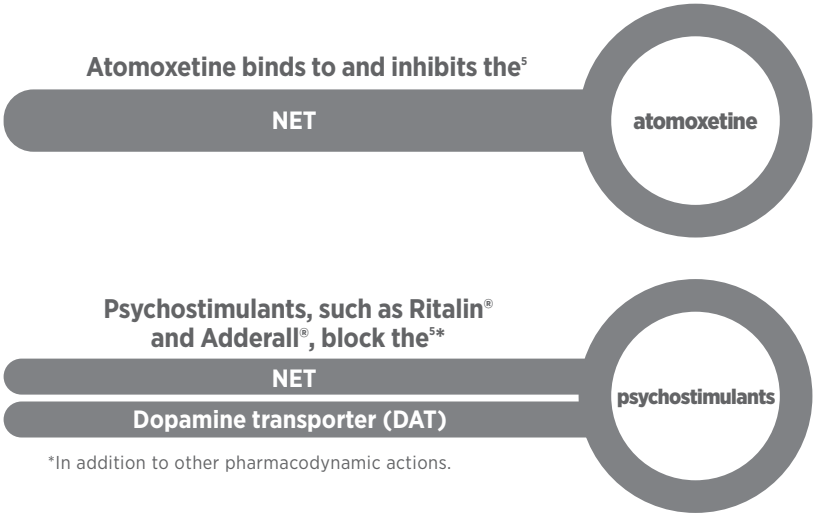
ONCE-DAILY Qelbree® viloxazine extended-release capsules 100 mg 150 mg 200 mg

For the treatment of ADHD in patients 6 years and older[1]...

Qelbree pharmacodynamics go beyond norepinephrine reuptake inhibition[1]

Qelbree is the first and only ADHD nonstimulant with a multimodal pharmacodynamic profile[1-4]

The pharmacodynamic activity of viloxazine is based on non-clinical studies and the clinical significance of the data is unknown. The mechanism of action of viloxazine in the treatment of ADHD is unclear; however, it is thought to be through inhibiting the reuptake of norepinephrine[1]



*In addition to other pharmacodynamic actions.

Abbreviation: ADHD, attention-deficit/hyperactivity disorder.

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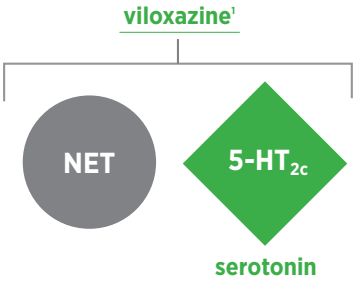
Qelbree[1]



- **Qelbree** inhibits NET, and exhibits partial agonism of the serotonin 5-HT_{2c} receptor[1,5]
- **Qelbree** is not a controlled substance[1]

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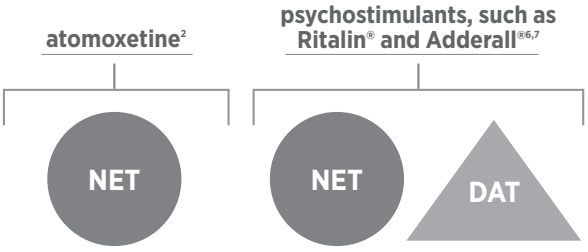
Other ADHD treatments[2,6,7]



- Atomoxetine inhibits NET[2]
- Psychostimulants, such as Ritalin and Adderall, block NET and DAT[6,7]*
  - –These medications impact DAT in the addiction regions of the brain, and are labeled as controlled substances[5-7]

*In addition to other pharmacodynamic actions.

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

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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 (≥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.