

Classical understanding of ADHD attributes symptoms to NE and DA imbalances in the PFC.¹

Reduced availability or inefficient signaling of NE and DA disrupt the ability of the PFC to filter distractions and sustain focus':

- ADHD medications aim to restore balance by increasing NE and DA availability through transporter inhibition (eg, NET or DAT inhibition)¹
- DAT inhibition with psychostimulants may lead to excess DA in the striatum, which can trigger addiction and/or dependence¹⁻³

Forward-looking evidence in the understanding of ADHD suggests that serotonin dysregulation may also contribute to symptoms⁴⁻⁸

In preclinical studies, selective serotonin receptor dysregulation has been associated with behaviors including:







Impulsivity⁵

Serotonin receptor modulation can be associated with

increasing NE and DA in the PFC.

Effective ADHD treatment may involve optimizing the balance and regulation of DA, NE, and serotonin (5-HT).

The information presented here is unrelated to the studies conducted for this product and is not intended to support specific claims about ADHD treatment with this product.

Break the cycle of multiple prescriptions and fast-forward through potential "pain points" this school year

A survey of 11,000 caregivers and adults revealed that finding the right ADHD treatment can be challenging.":

- It can be a frustrating period of trial and error
- The average child tries ~3 different medications"







*Survey conducted by ADDitude Magazine.

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.

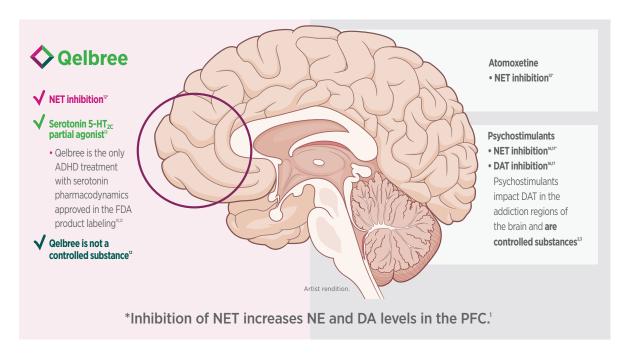
Please see full Important Safety Information on page 7.



This back-to-school season,

look forward to nonstimulant treatment that works!12

Qelbree is the first and only ADHD nonstimulant with a multimodal pharmacodynamic profile¹²⁻¹⁵



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 NE.¹²



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 7.

This back-to-school season,

look forward to ADHD nonstimulant treatment that works in children and teens 6 to 17 years of age¹²



Pediatric clinical trials

Methodology¹²: Randomized, DB, placebo-controlled, fixed-dose, parallel-group, multicenter studies of children 6 to 11 years of age with ADHD (Study P301 and P303) and teens 12 to 17 years of age (Study P302). **Primary endpoint**¹⁸: CFB in the ADHD-RS-5 Total Score at EOS. **Results**¹²: ADHD-RS-5 Total Scores at EOS were significantly reduced with Qelbree vs placebo. The CFB in ADHD-RS-5 Total Score at EOS (Study P301) (LS mean ± SE) was -16.6 ± 1.16 for Qelbree 100 mg/day, -17.7 ± 1.12 for Qelbree 200 mg/day, and -10.9 ± 1.14 for placebo. The CFB in ADHD-RS-5 Total Score at EOS (Study P302) (LS mean ± SE) was -16.0 ± 1.45 for Qelbree 200 mg/day, -16.5 ± 1.38 for Qelbree 400 mg/day, and -11.4 ± 1.37 for placebo.

Abbreviations: ADHD-RS-5, Attention-Deficit/Hyperactivity Disorder Rating Scale, 5th Edition; CFB, change from baseline; DB, double blind; EOS, end of study; LS mean, least-squares mean; SE, standard error.

IMPORTANT SAFETY INFORMATION

- 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
- 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



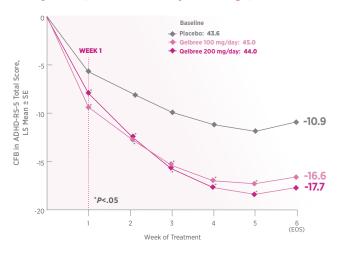
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This school year, look forward with Qelbree— a nonstimulant treatment that works for ADHD in children and teens 6 to 17 years of age¹²

Proven efficacy in treating ADHD at EOS (n=460)^{12,18}

Inattention and hyperactivity/impulsivity symptom score reductions observed as early as week 112,18

Study P301 (Children 6 to 11 years of age)



Study P301 results

Total Score at EOS was significantly reduced with Qelbree vs placebo.¹² The CFB in ADHD-RS-5 Total Score at EOS was -16.6 for Qelbree 100 mg/day, -17.7 for Qelbree 200 mg/day, and -10.9 for placebo.¹²

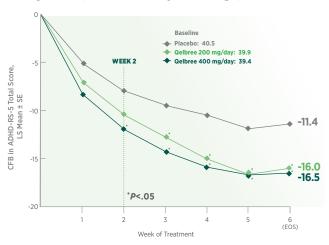


Titrate Qelbree 100 mg/week over 1 to 3 weeks as needed to reach effective dose.¹²

Proven efficacy in treating ADHD at EOS (n=301)¹²

Inattention and hyperactivity/impulsivity symptom score reductions observed as early as week 2^{12,19}

Study P302 (Teens 12 to 17 years of age)



Study P302 results

Total Score at EOS was significantly reduced with Qelbree vs placebo.¹² The CFB in ADHD-RS-5 Total Score at EOS was -16.0 for Qelbree 200 mg/day, -16.5 for Qelbree 400 mg/day, and -11.4 for placebo.¹²



Titrate Qelbree 200 mg/week over 1 week as needed to reach effective dose.¹²

INDICATION

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

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This school year, look forward with Qelbree—
a nonstimulant treatment that works for ADHD
in children and teens 6 to 17 years of age¹²

Speak with your representative about the resources

we provide to help you start the transition!

Patient Starter Kits



Patient Savings Program*



Samples









Get your patients off to a great start this school year.

Scan here to order Qelbree samples! Learn more at QelbreeHCP.com



^{*}Terms and conditions: Offer void where prohibited. For full terms and conditions, please see the Qelbree Co-pay Card, or visit www.Qelbree.com.

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

- 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) 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.

Please see full <u>Prescribing Information</u>, including Boxed Warning.

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