

**INDICATION**

Gelbree 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 Gelbree than in patients treated with placebo. Closely monitor all Gelbree-treated patients for clinical worsening and for emergence of suicidal thoughts and behaviors.**

Please see full Important Safety Information on page 2.

**FELICITY, 17 YEARS OLD**

Patient portrayal.

- **Current ADHD treatment:** None—recently discontinued low-dose extended-release AMP
- Her parents talked to her doctor about an adjustment to her ADHD treatment plan

Individual results may vary.

**CLINICAL CONSIDERATIONS:**

- Family history of anxiety and depression; initially diagnosed with ADHD at age 14

**FELICITY'S THERAPEUTIC HISTORY:**

- Treatment history:
  - Nonstimulant (switched due to lack of symptom improvement)
  - Extended-release MPH (switched due to tolerability concerns)
- Most recent treatment:
  - Extended-release AMP (several dose adjustments; parents reported “extreme avoidance,” both social and academic)

**FELICITY'S NEED FOR SYMPTOM IMPROVEMENT:**

- Overwhelmed and falling behind in classes; grades are slipping
- Distracted and unfocused in the evenings; unable to complete homework
- Late to school—misplaces books and lunch bag in the morning
- Forgets weekend plans; friends are frustrated with her
- Withdrawn behavior, lack of confidence; parents are concerned

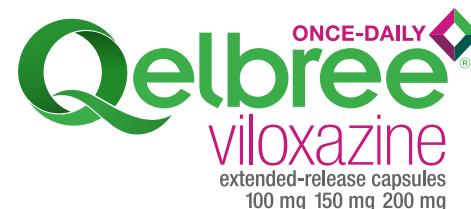
**CLINICAL TREATMENT WITH QELBREE:**

- Patient was started on Qelbree 200 mg/day
- During virtual check-in at week 2, patient reported improved symptom control but thought she could improve further; dose was titrated to Qelbree 400 mg/day
- At 1 month, Felicity seemed to tolerate Qelbree 400 mg/day and remained at this dose
- Patient no longer struggling mornings and evenings
- Parents report marked improvement in ability to complete schoolwork to her ability

Abbreviations: ADHD, attention-deficit/hyperactivity disorder; AMP, mixed amphetamine salts; MPH, methylphenidate.

**IMPORTANT SAFETY INFORMATION****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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## INDICATION

Qelbree® (viloxazine extended-release capsules) 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.**

## CONTRAINDICATIONS

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- 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 ( $\geq 5\%$  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).

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



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