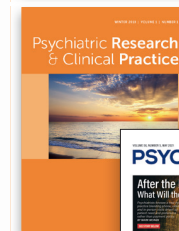
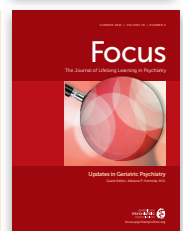
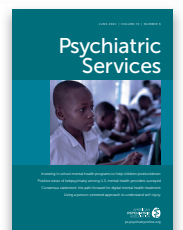
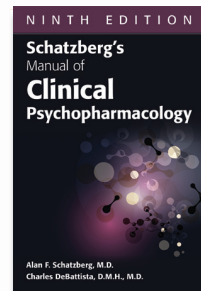
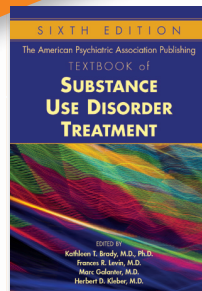
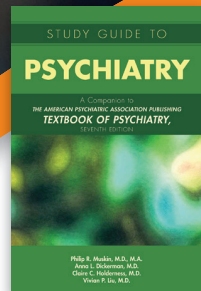
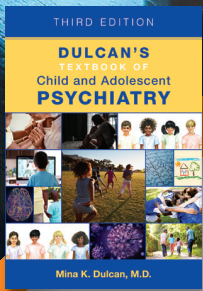
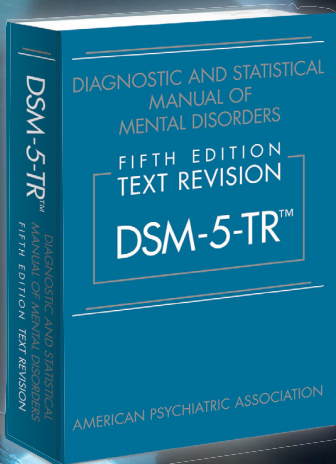


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**Qelbree® (viloxazine extended-release capsules), for oral use**  
**BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION**  
 For full prescribing information, see package insert.

**WARNING: SUICIDAL THOUGHTS AND BEHAVIORS**

**In clinical studies, higher rates of suicidal thoughts and behavior 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.**

**INDICATIONS AND USAGE**

Qelbree is indicated for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older.

**CONTRAINDICATIONS**

Qelbree is contraindicated in patients receiving concomitant treatment with monoamine oxidase inhibitors (MAOI), or within 14 days following discontinuing an MAOI, because of an increased risk of hypertensive crisis. Qelbree should not be taken when receiving concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range.

**WARNINGS AND PRECAUTIONS**

**Suicidal Thoughts and Behaviors**

Higher rates of suicidal thoughts and behaviors were reported in pediatric and adult patients with ADHD treated with Qelbree than in patients treated with placebo.

Among 1019 patients exposed to Qelbree 100 mg to 400 mg in short-term trials, a total of nine patients (0.9%) reported suicidal ideation (N=6), behavior (N=1) or both (N=2). Eight patients reported suicidal ideation or behavior on the Columbia Suicide Severity Rating Scale (C-SSRS), a validated scale that assesses suicide risk. An additional patient treated with Qelbree reported suicidal behavior during the clinical trials, but did not report it on the C-SSRS. Among 463 patients treated with placebo in these studies, two patients (0.4%) reported suicidal ideation on the C-SSRS. No patients treated with placebo reported suicidal behavior. No completed suicides occurred in these trials.

Among 189 adults treated with Qelbree, a total of three patients (1.6%) reported suicidal ideation on the C-SSRS, versus 0 of 183 adults treated with placebo. No adults treated with either Qelbree or placebo reported suicidal behavior on the C-SSRS in the study. No attempted or completed suicides occurred in the trial.

Patients treated with Qelbree had higher rates of insomnia and irritability. Although a causal link between the emergence of insomnia and irritability and the emergence of suicidal impulses has not been established, there is a concern that these and other symptoms such as depressed mood, anxiety, agitation, akathisia, mania, hypomania, panic attacks, impulsive behavior, and aggression may represent precursors to emerging suicidal ideation or behavior. Thus, patients being treated with Qelbree should be observed for the emergence of precursor symptoms.

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.

Consider changing the therapeutic regimen, including possibly discontinuing Qelbree, in patients who are experiencing emergent suicidal thoughts and behaviors or symptoms that might be precursors to emerging suicidal ideation or behavior, especially if these symptoms are severe or abrupt in onset, or were not part of the patient's presenting symptoms. Advise family members or caregivers of patients to monitor for the emergence of suicidal ideation or behavior, and to report such symptoms immediately to the healthcare provider.

**Effects on Blood Pressure and Heart Rate**

Qelbree can cause an increase in heart rate and diastolic blood pressure.

In a clinical study in patients 6 to 11 years of age, 34/154 (22%) of patients treated with Qelbree 100 mg daily had a  $\geq 20$  beat per minute (bpm) increase in heart rate at any time point in the clinical trial, compared to 15/159 (9%) of patients who received placebo. This finding was observed in 84/268 (31%) who received the 200 mg dose, compared to 39/262 (15%) of patients in the placebo group, and in 28/100 (28%) of patients who received the 400 mg dose, compared to 24/103 (23%) of patients who received placebo.

In a clinical study in patients 12 to 17 years of age, 22/99 (22%) of patients treated with Qelbree 200 mg daily had a  $\geq 20$  bpm increase in heart rate at any time point in the clinical trial, compared to 15/104 (14%) of patients who received placebo. This finding was observed in 69/205 (34%) who received the 400 mg dose, compared to 35/201 (17%) of patients in the placebo group.

In patients ages 12 to 17 years, 52/205 (25%) of patients treated with Qelbree 400 mg daily had a  $\geq 15$  mmHg increase in diastolic blood pressure at any time in the clinical trial, compared to 26/201 (13%) of patients in the placebo group.

In a clinical study in adult patients (18 to 60 years of age), 52/178 (29%) of patients treated daily with Qelbree (200 mg to 600 mg) had a  $\geq 20$  beat per minute (bpm) increase in heart rate at any time point in the clinical trial, compared to 23/181 (13%) of patients who received placebo. Of patients treated daily with Qelbree (200 to 600 mg), 23/178 (13%) had a  $\geq 15$  mmHg increase in diastolic blood

pressure at any time in the clinical trial, compared to 16/181 (9%) of patients in the placebo group.

Assess heart rate and blood pressure prior to initiating treatment with Qelbree, following increases in dosage, and periodically while on therapy.

**Activation of Mania or Hypomania**

Noradrenergic drugs, such as Qelbree, 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; such screening should include a detailed psychiatric history, including a personal or family history of suicide, bipolar disorder, and depression.

**Somnolence and Fatigue**

Qelbree can cause somnolence and fatigue. In the short-term, placebo-controlled clinical trials in pediatric patients 6 to 17 years of age with ADHD, somnolence (including lethargy and sedation) was reported in 16% of Qelbree-treated patients compared to 4% of placebo-treated patients. Fatigue was reported in 6% of Qelbree-treated patients compared to 2% of placebo-treated patients.

In adults, somnolence was reported in 6% of Qelbree-treated patients versus 2% in placebo-treated patients. Fatigue was reported in 12% of Qelbree-treated patients versus 3% of placebo-treated patients.

Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by Qelbree.

**ADVERSE REACTIONS**

**Clinical Trials Experience**

The safety of Qelbree has been evaluated in 1118 patients 6 to 17 years of age with ADHD exposed to one or more doses in short-term (6 to 8 week), randomized, double-blind, placebo-controlled trials.

A total of 682 pediatric patients were treated for at least 6 months, and 347 pediatric patients for at least 12 months with Qelbree.

The safety of Qelbree has been evaluated in 189 adult patients (18 to 60 years of age) with ADHD exposed to one or more doses in a short-term (6 week), randomized, double-blind, placebo-controlled trial. A total of 277 adult patients with ADHD have been exposed to one or more doses of Qelbree.

Eighty-four adult patients were treated for at least 6 months, and 22 adult patients for at least 12 months.

The data described below reflect exposure to Qelbree in 826 patients (6 to 17 years) who participated in randomized, double-blind, placebo-controlled trials with doses ranging from 100 mg to 400 mg. The population (N=826) was 65% male, 35% female, 54% White, 41% Black, 4% multiracial, and 1% other races.

**Adverse Reactions Leading to Discontinuation of Qelbree Treatment:**

Approximately 3% (n=27) of the 826 patients receiving Qelbree in clinical studies discontinued treatment due to an adverse reaction. The adverse reactions most commonly associated with discontinuation of Qelbree were somnolence (n=5), nausea (n=3), headache (n=2), irritability (n=2), tachycardia (n=2), fatigue (n=2), and decreased appetite (n=2).

*Most Common Adverse Reactions (occurring at  $\geq 5\%$  and at least twice the placebo rate for any dose):* somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability.

Tables 1 and 2 below lists adverse reactions that occurred in at least 2% of patients treated with Qelbree and more frequently in Qelbree-treated patients than in placebo-treated patients. Table 1 data represents pooled data from pediatric patients 6-17 years of age who were enrolled in randomized, placebo-controlled trials of Qelbree. Table 2 represents data from adults with ADHD who were enrolled in a flexible-dose, randomized, placebo-controlled trial of Qelbree at doses of 200mg to 600mg.

**Table 1. Adverse Reactions Reported in  $\geq 2\%$  of Pediatric Patients (6 to 17 Years of Age) Treated with Qelbree and at a Rate of Greater than Placebo-Treated Patients in Placebo-Controlled ADHD Studies**

Body System Adverse Reaction	Placebo N=463 (%)	Qelbree			
		100mg N=154 (%)	200mg N=367 (%)	400mg N=305 (%)	All Qelbree N=836 (%)
<b>Nervous system disorders</b>					
Somnolence*	4	12	16	19	16
Headache*	7	10	11	11	11
<b>Metabolic and nutritional disorders</b>					
Decreased appetite	0.4	5	8	8	7
<b>Infections and infestations</b>					
Upper respiratory tract infections*	6	5	7	8	7
<b>Body as a Whole - General disorders</b>					
Fatigue	2	4	5	9	6
Pyrexia	0.2	3	2	1	2
<b>Gastrointestinal system disorders</b>					
Abdominal Pain*	4	3	6	7	5
Nausea	3	1	4	7	5
Vomiting	2	5	3	6	4

**Table 1. Adverse Reactions Reported in ≥2% of Pediatric Patients (6 to 17 Years of Age) Treated with Qelbree and at a Rate Greater than Placebo-Treated Patients in Placebo-Controlled ADHD Studies (continued)**

Body System Adverse Reaction	Placebo N=463 (%)	Qelbree			
		100mg N=154 (%)	200mg N=367 (%)	400mg N=305 (%)	All Qelbree N=836 (%)
<b>Psychiatric disorders</b>					
Insomnia*	1	2	5	5	4
Irritability	1	3	2	5	3

\*The following items were combined:

**Somnolence:** somnolence, lethargy, sedation

**Headache:** headache, migraine, migraine with aura, tension headache

**Upper respiratory tract infection:** nasopharyngitis, pharyngitis, sinusitis, upper respiratory tract infection, viral sinusitis, viral upper respiratory tract infection

**Abdominal pain:** abdominal discomfort, abdominal pain, abdominal pain lower, abdominal pain upper

**Insomnia:** initial insomnia, insomnia, middle insomnia, poor quality sleep, sleep disorder, terminal insomnia

The data described below reflect exposure to Qelbree in 189 adults with ADHD who participated in the flexible-dose, randomized, double-blind, placebo-controlled trial with doses ranging from 200 mg to 600 mg. The population (N=189) was 56% male, 44% female, 81% White, 12% Black, 3% Asian, 3% other races and 1% multiracial.

**Adverse Reactions Leading to Discontinuation of Qelbree Treatment:**

Approximately 9% of the 189 patients receiving Qelbree in clinical studies discontinued treatment due to an adverse reaction. The adverse reactions most commonly associated with discontinuation of Qelbree were fatigue (n=4), insomnia (n=3), constipation (n=3), and headache (n=2).

**Most Common Adverse Reactions (occurring at ≥5% and at least twice the placebo rate of Qelbree):** insomnia, headache, somnolence, fatigue, nausea, decreased appetite, dry mouth, and constipation.

Listed here are adverse reactions that occurred in at least 2% of patients treated with Qelbree and more frequently in the Qelbree-treated patients than in the placebo-treated patients. Table 2 represents data from adults with ADHD who were enrolled in a flexible-dose, randomized, placebo-controlled trial of Qelbree at doses of 200 mg to 600 mg.

**Table 2. Adverse Reactions Reported in ≥2% of Adults Treated with Qelbree and at a Rate Greater than Placebo-Treated Patients in a Flexible-Dose Placebo-Controlled ADHD Study**

Body System Adverse Reaction	Placebo N=183 (%)	Qelbree (200 mg to 600 mg) N=189 (%)
<b>Psychiatric disorders</b>		
Insomnia*	7	23
Irritability	3	4
<b>Nervous system disorders</b>		
Headache*	7	17
Somnolence*	2	6
Dizziness	2	4
<b>Gastrointestinal system disorders</b>		
Nausea	3	12
Dry mouth	2	10
Constipation	1	6
Vomiting	1	4
Gastroesophageal reflux disease	1	2
<b>Body as a Whole - General disorders</b>		
Fatigue	3	12
<b>Metabolic and nutritional disorders</b>		
Decreased appetite	3	10
<b>Cardiac disorders</b>		
Tachycardia	1	4

\*The following items were combined:

**Somnolence:** somnolence, lethargy, sedation

**Headache:** headache, migraine, migraine with aura, tension headache

**Insomnia:** initial insomnia, insomnia, middle insomnia, poor quality sleep, sleep disorder, terminal insomnia

## DRUG INTERACTIONS

### Drugs Having Clinically Important Interactions with Qelbree

#### Monoamine Oxidase Inhibitors (MAOI)

- Clinical Impact: Concomitant use of Qelbree with an MAOI may lead to a potentially life-threatening hypertensive crisis.
- Intervention: Concomitant use of Qelbree with an MAOI or within 2 weeks after discontinuing an MAOI is contraindicated.

#### Sensitive CYP1A2 Substrates or CYP1A2 Substrates with a Narrow Therapeutic Range

- Clinical Impact: Viloxazine is a strong CYP1A2 inhibitor. Concomitant use of viloxazine significantly increases the total exposure, but not peak exposure, of

sensitive CYP1A2 substrates, which may increase the risk of adverse reactions associated with these CYP1A2 substrates.

- Intervention: Coadministration with Qelbree is contraindicated.

#### Moderate Sensitive CYP1A2 Substrate

- Clinical Impact: Viloxazine is a strong CYP1A2 inhibitor. Concomitant use of viloxazine significantly increases the total, but not peak, exposure of sensitive CYP1A2 substrates, which may increase the risk of adverse reactions associated with these CYP1A2 substrates.

- Intervention: Not recommended for coadministration with Qelbree. Dose reduction may be warranted if coadministered.

#### CYP2D6 Substrates

- Clinical Impact: Viloxazine is a weak inhibitor of CYP2D6, and increases the exposure of CYP2D6 substrates when coadministered.
- Intervention: Monitor patients for adverse reactions and adjust dosages of CYP2D6 substrates, as clinically indicated.

#### CYP3A4 Substrates

- Clinical Impact: Viloxazine is a weak inhibitor of CYP3A4 which increases the exposure of CYP3A4 substrates when coadministered.
- Intervention: Monitor patients for adverse reactions and adjust dosages of CYP3A4 substrates, as clinically indicated.

## USE IN SPECIFIC POPULATIONS

### Pregnancy

#### Pregnancy Exposure Registry

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 visiting online at [www.womensmentalhealth.org/peg](http://www.womensmentalhealth.org/peg).

#### Risk Summary

Based on findings from animal reproduction studies, viloxazine may cause maternal harm when used during pregnancy. Discontinue Qelbree when pregnancy is recognized unless the benefits of therapy outweigh the potential risk to the mother. Available data from case series with viloxazine use in pregnant women are insufficient to determine a drug-associated risk of major birth defects, miscarriage or adverse maternal outcomes.

In animal reproduction studies, oral administration of viloxazine during the period of organogenesis caused fetal toxicities and delayed fetal development in the rat and maternal toxicities in the rabbit at doses approximately equal to the maximum recommended human dose (MRHD) of 600mg in adults, based on mg/m<sup>2</sup>. Oral administration of viloxazine to pregnant rats and mice during pregnancy and lactation caused maternal toxicities and deaths and fetal toxicities at doses equal to or less than the MRHD of 600mg in adults, based on mg/m<sup>2</sup>, respectively.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcome. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

#### Lactation

##### Risk Summary

There are no data on the presence of viloxazine in human milk, the effects on the breastfed infant, or the effects on milk production. Viloxazine is likely present in rat milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk.

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.

#### Geriatric Use

Clinical trials of Qelbree in the treatment of ADHD did not include sufficient numbers of patients aged 65 and older to determine whether or not they respond differently from younger patients.

#### Renal Impairment

Dosage reduction is recommended in patients with severe (eGFR of < 30 mL/min/1.73m<sup>2</sup> [MDRD]) renal impairment.

No dosage adjustment of Qelbree is recommended in patients with mild to moderate (eGFR of 30 to 89 mL/min/1.73m<sup>2</sup> [MDRD]) renal impairment.

The exposure of viloxazine increases in patients with renal impairment.

## OVERDOSAGE

### Human Experience

The pre-market clinical trials with Qelbree do not provide information regarding symptoms of overdose.

Literature reports from post marketing experience with immediate-release viloxazine include cases of overdose from 1000 mg to 6500 mg (1.7 to 10.8 times the maximum recommended daily dose). The most reported symptom was drowsiness. Impaired consciousness, diminished reflexes, and increased heart rate have also been reported.

### Treatment and Management

There is no specific antidote for Qelbree overdose. Administer symptomatic and supportive treatment as appropriate. In case of overdose, consult a Certified Poison Control Center (1-800-222-1222 or [www.poison.org](http://www.poison.org)).



Patient portrayals.

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IN ADULTS AND  
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100 mg 150 mg 200 mg  
**Rethink ADHD Symptom Control**

## 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.**

## 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 ( $\geq 5\%$  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).

Abbreviation: ADHD, attention-deficit/hyperactivity disorder.

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**Please see the brief summary of full Prescribing Information, including Boxed Warning, on adjacent pages, or visit [QelbreeHCP.com](http://QelbreeHCP.com).**



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