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ONCE-DAILY

Qelbree®

viloxazine

extended-release capsules

100 mg 150 mg 200 mg

Today's fastest growing ADHD Rx Brand*

A novel nonstimulant that works for ADHD in patients 6 years and older[2,3]

- 24-hour exposure to medication in a single daily dose—can be dosed AM or PM[1,2]
- Straightforward weekly titration to optimal dose in as little as 2 weeks[2]

***Branded ADHD products launched in last 6 years (as of September 2023).**

Abbreviation: ADHD, attention-deficit/hyperactivity disorder.

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.

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

A novel nonstimulant that works for ADHD in patients 6 years and older[2,3]

24 HOURS

Prescribed once daily (AM or PM) for full 24-hour exposure[1,2]

Qelbree can be conveniently prescribed and refilled without a new prescription every month.

IMPORTANT SAFETY INFORMATION

- *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
- *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

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CHILDREN (6 to 11 years)
Start at Qelbree 100 mg/day[2]

Maximum dose **400 mg/day[2]**

Titrate Qelbree 100 mg/week over 1 to 3 weeks **as needed to reach effective dose[2]**

3 easy steps to support patient transition to their best dose; initiate treatment today![2]*

Step 1: Provide patient with a starter kit and $20 co-pay card† (included); provide a 300 mg Rx for Qelbree (viloxazine extended-release capsules).

Step 2: Evaluate patient weekly to optimize dose of Qelbree. Check in with the parent directly to evaluate 300 mg dose.

Step 3: Prescribe optimized maintenance dose of Qelbree.

Initiation[2]

Week 1 ► Week 2

SPN 100
100 mg QD
(starting dose)

SPN 200
200 mg QD

Leave first visit with Rx for Week 3 optimization

Transition and dose optimization phase[2]

SPN 150
SPN 150
300 mg QD

Maintenance[2]

HCP/office staff phone follow-up

Actor portrayal.

Titrate weekly as needed to optimize ADHD symptom control, up to **400 mg QD (max dose).**[2]

SPN 200
SPN 200
400 mg QD
(max dose)

Titrate weekly as needed—100 mg per week over 1 to 3 weeks.[2]

Capsules shown are not actual size.
*The HCP will determine course of titration.
†Terms and conditions apply.
Abbreviation: HCP, healthcare professional.

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TEENS (12 to 17 years)
Start at Qelbree 200 mg/day[2]

Titrate Qelbree 200 mg/week over 1 week **as needed to reach effective dose[2]**

Maximum dose 400 mg/day[2]

3 easy steps to support patient transition to their best dose; initiate treatment today![2*]

Step 1: Provide patient with a starter kit and $20 co-pay card† (included); provide a 400 mg Rx for Qelbree (viloxazine extended-release capsules).

Step 2: Evaluate patient weekly to optimize dose of Qelbree. Check in with the parent directly to evaluate 400 mg dose.

Step 3: Prescribe optimized maintenance dose of Qelbree.

Initiation[2]

Week 1 ••••••► Week 2

200 mg QD
(starting dose)

400 mg QD
(max dose)

Transition and dose optimization phase[2]

Leave first visit with Rx for Week 3 optimization

400 mg QD

Maintenance[2]

HCP/office staff phone follow-up

Actor portrayal.

Titrate weekly as needed to optimize ADHD symptom control, up to **400 mg QD (max dose).**[2]

400 mg QD
(max dose)

Titrate weekly as needed—200 mg per week over 1 week.[2]

Capsules shown are not actual size.
*The HCP will determine course of titration.
†Terms and conditions apply.

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ADULTS (18 and older)
Start at Qelbree 200 mg/day[2]

Titrate Qelbree 200 mg/week over 1 to 2 weeks **as needed to reach effective dose[2]**

400 mg/day[2] **TO** **Maximum dose 600 mg/day[2]**

Adult phase III (Study P306): Mean dose at EOS (6 weeks) was 504 mg/day (n=354)[1]

3 easy steps to support patient transition to their best dose; initiate treatment today![2]*

Step 1: Provide patient with a starter kit and $20 co-pay card† (included); provide a 400 mg Rx for Qelbree (viloxazine extended-release capsules).

Step 2: Evaluate patient weekly to optimize dose of Qelbree.

Step 3: Prescribe optimized maintenance dose of Qelbree.

Initiation[2]

Week 1 ► Week 2

200 mg QD (starting dose)

400 mg QD

Transition and dose optimization phase[2]

Leave first visit with Rx for Week 3 optimization

400 mg QD

Maintenance[2]

HCP/office staff phone follow-up

Actor portrayal.

Titrate weekly as needed to optimize ADHD symptom control, up to **600 mg QD (max dose)**.[2]

600 mg QD (max dose)

Titrate weekly as needed—200 mg per week over 1 to 2 weeks.[2]

Capsules shown are not actual size.

*The HCP will determine course of titration.
†Terms and conditions apply.
Abbreviation: EOS, end of study.

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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 (≥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. Data on file, Supernus Pharmaceuticals. **2.** Qelbree [package insert], Rockville, MD: Supernus Pharmaceuticals, Inc. **3.** Food and Drug Administration. Novel drug approvals for 2021. May 13, 2022. Accessed January 7, 2023. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2021.

Please see full Prescribing Information, including Boxed Warning.

LINKS TO: https://www.supernus.com/sites/default/files/Qelbree-Prescribing-Info.pdf

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

Supernus® Pharmaceuticals