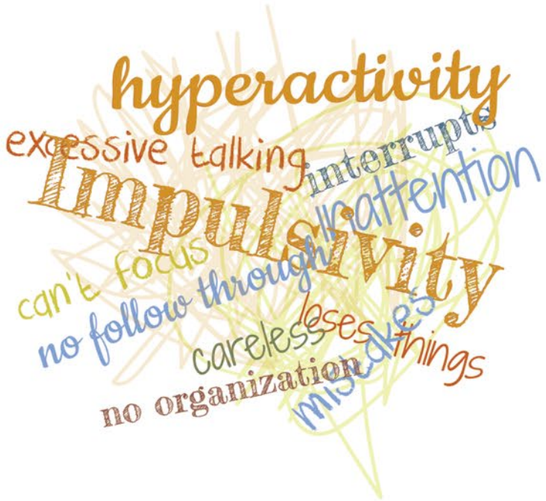
INTRODUCING

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

The first new chemical entity launched in ADHD in over a decade[1,2]



Less chaos

All photos within this piece are patient portrayals.

More control[1,3]

INDICATION

Qelbree is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in pediatric patients ages 6 to 17.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

In clinical studies, higher rates of suicidal thoughts and behaviors were reported in pediatric 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 Prescribing Information and additional Important Safety Information.

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

Rethink ADHD Symptom Control™

ADHD is one of the most common neurodevelopmental disorders diagnosed in children and adolescents.[4]

- An estimated **6.1 million** US children and adolescents are diagnosed with ADHD[5]
  - —62% are on medication to manage their ADHD[5]
  - —Stimulants make up a majority of prescriptions, per recommended guidelines[6,7]

No new chemical entities have been approved to treat ADHD in over a decade.[1,2]

Do you have pediatric and adolescent patients with ADHD who are not getting the desired response on their current medication(s)?

INTRODUCING a new nonscheduled approach to ADHD multisymptom control[1]...

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The first new chemical entity launched in ADHD in over a decade[1,2]

NEW ONCE-DAILY Qelbree

IMPORTANT SAFETY INFORMATION (CONT'D)

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

- *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 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) were somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, and irritability.

DOSING SAFETY INFORMATION

- Swallow Qelbree capsules whole or sprinkle entire contents on a teaspoonful of applesauce and consume all within 2 hours, without regard to meals. Do not cut, crush, or chew the capsules
- 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
- Prior to initiating treatment, screen for a history of suicide, bipolar disorder and depression
- Prior to initiating treatment, following increases in dosage, and periodically during therapy, measure heart rate and blood pressure
- Qelbree is a strong CYP1A2 inhibitor. Coadministration with moderately sensitive CYP1A2 substrates (eg, clozapine and pirfenidone) is not recommended. If coadministered, dose reduction may be warranted
- Qelbree is a weak inhibitor of CYP2D6 and CYP3A4, which increases exposure of those substrates (eg, dextromethorphan and alfentanil) when coadministered with Qelbree. Monitor patients for adverse reactions and adjust dosages of substrates as clinically indicated
  –For a more complete list of drug-to-drug interactions, including clinical effects and examples, please see table 2 in section 7 of the full Prescribing Information

PREGNANCY & LACTATION

- Qelbree may cause maternal harm. It is not known if Qelbree passes into breastmilk or if Qelbree has an effect on the breastfed infant. Discontinue Qelbree if the risks of therapy during pregnancy outweigh the benefits

Please see full Prescribing Information, including Boxed Warning.

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The first new chemical entity launched in ADHD in over a decade[1,2]

NEW ONCE-DAILY Qelbree

A novel, nonscheduled option, and an easy addition to your ADHD treatment choices[1]

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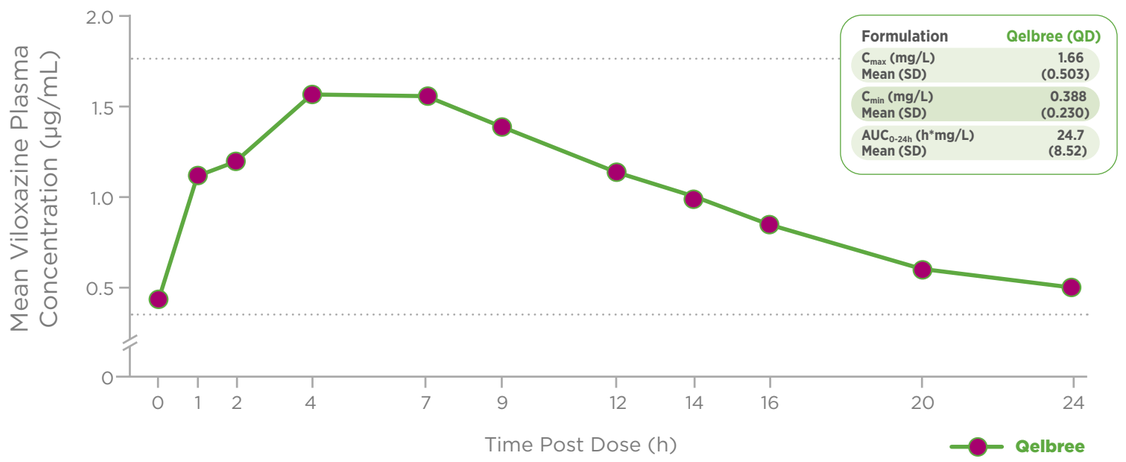
Rethink ADHD Symptom Control™

Qelbree—Rapid and extended release; nonscheduled, full-day exposure[1,6]

Once-daily Qelbree—24-hour mean SS plasma concentration–time profile (N=28)[1,6]



- Reached SS at day 2[6]
- Duration of exposure that lasts throughout the day[6]
- Demonstrated gradual release of an ER formulation[6]

Abbreviations: AUC, area under the curve; C_{max}, maximum serum concentration; C_{min}, minimum serum concentration; ER, extended release; SS, steady state.

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NEW ONCE-DAILY Qelbree

Phase III clinical trials* designed to establish efficacy and safety in patients 6 to 17 years of age (n=826)[1]

Overview: clinical trials, study design, and methodology[6]

	Pediatric (6 to 11 years of age)		Adolescent (12 to 17 years of age)
Clinical trial	P301	P303	P302
ITT population (N)	460	301	301
Clinical trial dosing	100 mg, 200 mg	200 mg, 400 mg	200 mg, 400 mg
Duration of trial/weeks (Titration period + maintenance period)	6 Weeks (1+5)	8 Weeks (3+5)	6 Weeks (1+5)

Phase III trials methodology[1,6]: all clinical trials were randomized, double-blind, placebo-controlled, 3-arm, parallel-group, multicenter studies. **Primary endpoint:** CFB in the ADHD-RS-5 total score at EOS, Qelbree treatment group. **Inclusion criteria to include:** males and females; children 6 to 11 years/adolescents 12 to 17 years; ADHD diagnosis based on criteria in the DSM-5, confirmed with the MINI-KID; ADHD-RS-5 total score of ≥28; CGI-S ≥4. **Exclusion criteria to include:** major psychiatric disorder (MDD history allowed); major neurobiological disorder; history of seizures; significant systemic disease; evidence of suicidality within prior 6 months before screening.

*Primary analysis is based on ITT population.[6]
Study P301 EOS=Week 6; Study P303 EOS=Week 8; Study P302 EOS=Week 6.[1]

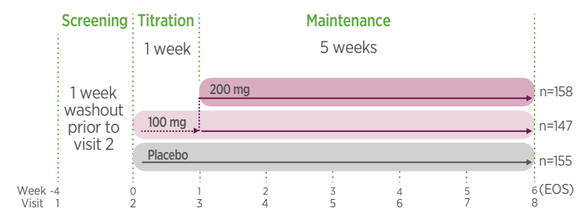
Abbreviations: ADHD-RS-5=Attention-Deficit/Hyperactivity Disorder Rating Scale, 5th Edition; CFB=change from baseline; CGI-S=Clinical Global Impression–Severity of Illness; DSM-5, *Diagnostic and Statistical Manual of Mental Disorders*, 5th edition; EOS, end of study; ITT, intention to treat; MDD, major depressive disorder; MINI-KID, Mini-International Neuropsychiatric Interview for Children and Adolescents.

Please see full Prescribing Information, including Boxed Warning and Important Safety Information.

Clinical trial protocol: study design schematic[1,6]

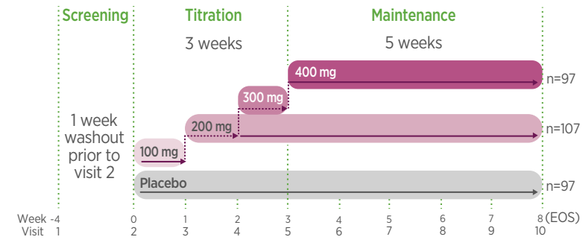
P301: Children, 6 to 11 years of age[1,6]

Age group: 6 to 11 years of age
ITT population: N=460
Study medication: 100 mg capsule or matching placebo



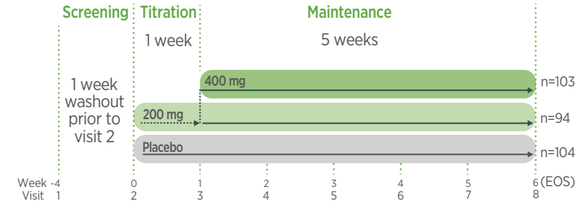
P303: Children, 6 to 11 years of age[1,6]

Age group: 6 to 11 years of age
ITT population: N=301
Study medication: 100 mg capsule or matching placebo



P302: Adolescents, 12 to 17 years of age[1,6]

Age group: 12 to 17 years of age
ITT population: N=301
Study medication: 200 mg capsule or matching placebo



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

Rethink ADHD Symptom Control™

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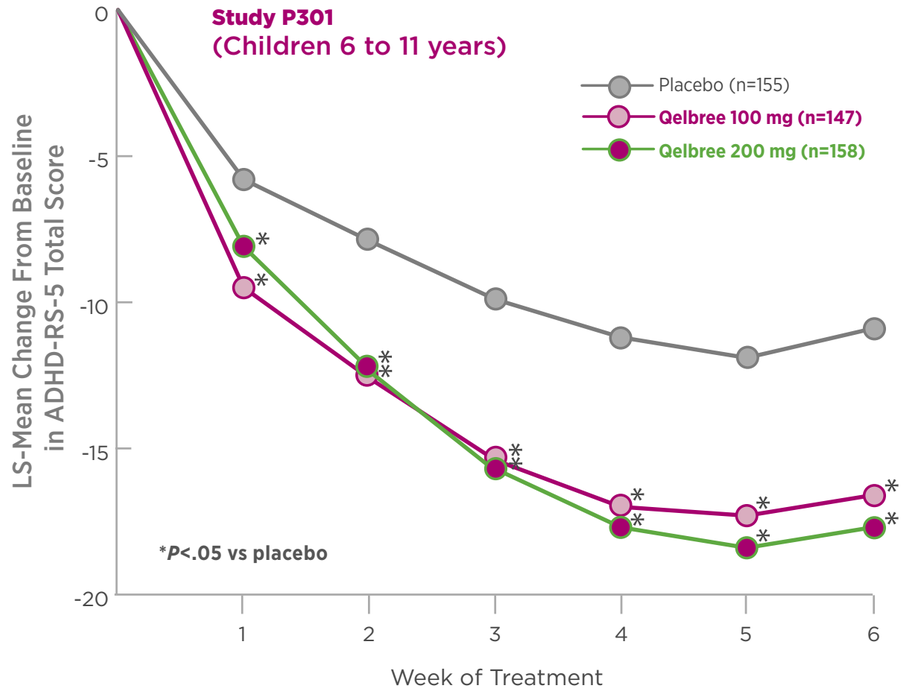
The first new chemical entity launched in ADHD in over a decade[1,2]

NEW ONCE-DAILY Qelbree

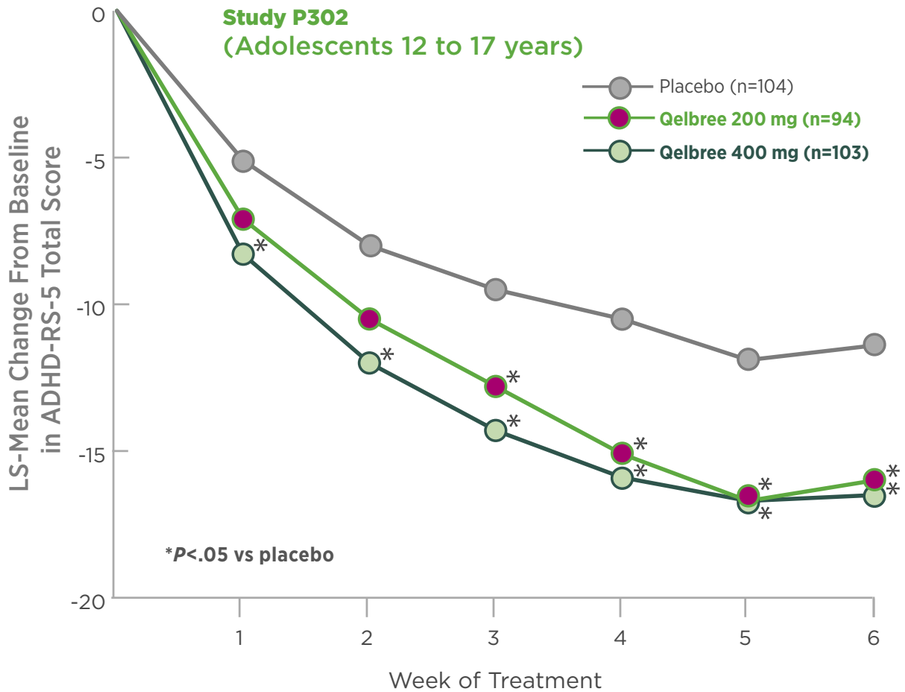
Proven efficacy in treating ADHD (N=460)[1]

Improvement in symptoms of inattention, hyperactivity, and impulsivity consistently observed as early as week 1[1,6]



Proven efficacy in treating ADHD (N=301)[1]

Improvement in symptoms of inattention, hyperactivity, and impulsivity consistently observed as early as week 1[1,6]



Study P301 results Total score at EOS was significantly reduced with Qelbree vs placebo. The CFB in ADHD-RS-5 total score at EOS (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.[6]

Study P302 results Total score at EOS was significantly reduced with Qelbree vs placebo. The CFB in ADHD-RS-5 total score at EOS (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.[6]

Study P303 results Proven efficacy in treating ADHD (n=301): Total score at EOS was significantly reduced with Qelbree vs placebo. The CFB in the ADHD-RS-5 total score (LS mean ± SE) was -17.6 ± 1.43 for Qelbree 200 mg/day, -17.5 ± 1.52 for Qelbree 400 mg/day, and -11.7 ± 1.48 for placebo.[1,6]

- **Once-daily Qelbree delivers a significant effect on the subscales of both inattention and hyperactivity/impulsivity in children and adolescents[6]**
- **Once-daily Qelbree demonstrates proven safety and tolerability and low discontinuation rates due to AEs in children and adolescents[1,6]**

Abbreviations: AEs, adverse events; LS mean, least squares mean; SE, standard error.

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The first new chemical entity launched in ADHD in over a decade[1,2]

NEW ONCE-DAILY Qelbree

Qelbree—Proven safety and tolerability across phase III clinical trials in ADHD patients 6 to 17 years of age (n=826)[1]

The most common AEs* (≥5% and twice the rate of placebo) reported by children and adolescents (ages 6 to 17)[1]

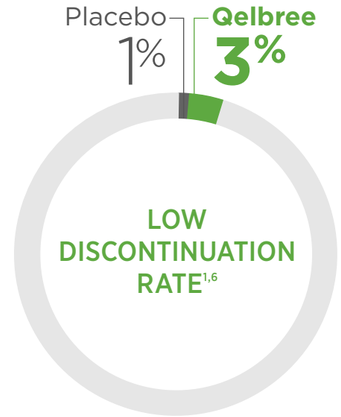
	Placebo (n=463)	Qelbree (n=826)
Somnolence†	4%	16%
Decreased appetite	0.4%	7%
Fatigue	2%	6%

*TEAEs.
† Somnolence: somnolence, lethargy, sedation.[1]

Abbreviations: DDI, drug-drug interaction; TEAEs, treatment-emergent adverse events.

Qelbree—Low discontinuation rates in pediatric and adolescent trials (n=826)[1]

Discontinuation rates due to AEs across all phase III trials and safety profile[1]



Qelbree safety profile

- Viloxazine is unlikely to have a DDI with amphetamines[1]
- Viloxazine is unlikely to have a DDI with methylphenidate[1]
- No clinically relevant liver enzyme elevation[6]

Because clinical trials are conducted under widely varying conditions, AE rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

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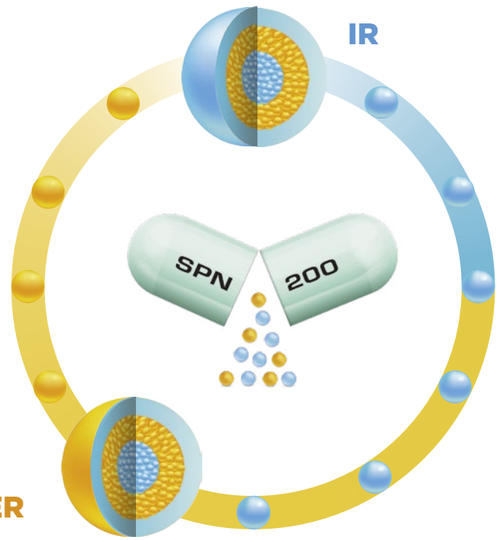
The first new chemical entity launched in ADHD in over a decade[1,2]

NEW ONCE-DAILY Qelbree

The first 2-bead Microtrol™ Technology delivery of nonscheduled viloxazine for 24-hour patient exposure[1,6]



Artist rendition.

Once-daily Qelbree shows no evidence of abuse potential in studies—minimizing risk of treatment abuse, misuse, or diversion.[6,8]

- Viloxazine was found to be free of physical drug dependence in 5 animal models of abuse liability[8]
- No withdrawal symptoms or signs of dependence were reported as AEs during human clinical trials[6]

Nonscheduled approach to multisymptom ADHD control[1]

✔ **Can be conveniently sampled, prescribed, and refilled without a new prescription every month**

Abbreviation: IR, immediate release.

Please see full Prescribing Information, including Boxed Warning and Important Safety Information.

Once-daily Qelbree— Straightforward, convenient dosing; easy administration and titration[1]

Tailored dosing to meet the needs of your patients

Administration

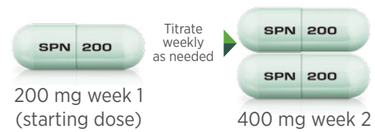
Capsule can be taken whole, or capsule can be opened and its entire contents sprinkled onto a teaspoonful of applesauce and all consumed within 2 hours.[1]

- Capsules and their contents should not be cut, crushed, or chewed[1]

Titration

Children 6 to 11[1]

Adolescents 12 to 17[1]



- Once-daily oral administration[1]
- Capsules may be taken with or without food[1]

Maximum dose for children and adolescents is 400 mg daily[1]

Qelbree capsules are available in 3 dosage strengths.[1]

Dosing safety information[1]

- 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
- Prior to initiating treatment, screen for a history of suicide, bipolar disorder, and depression
- Prior to initiating treatment, following increases in dosage, and periodically during therapy, measure heart rate and blood pressure

Please see additional dosing safety information.

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The first new chemical entity launched in ADHD in over a decade[1,2]

NEW ONCE-DAILY Qelbree

The Qelbree team is committed to supporting ADHD patients and their families

Comprehensive sample and support programs

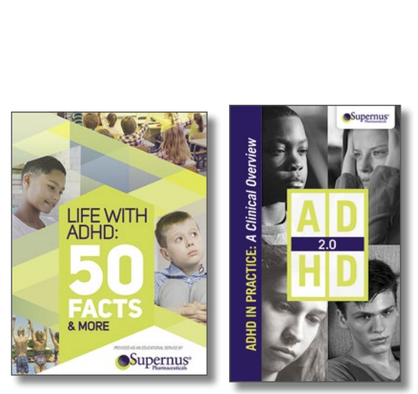
Patient Starter Kit

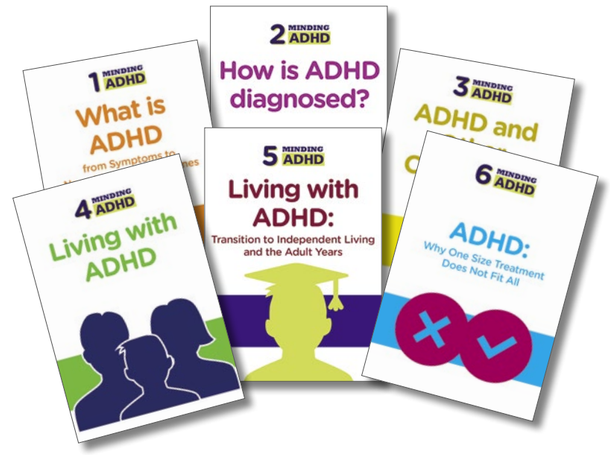
Supernus® Support 1-866-398-0833

covermymeds®

The Qelbree team is committed to advancing the treatment, education, and management of ADHD

The Qelbree team is pleased to provide a breadth of resources that cover the topics families ask about most:





Supernus® Pharmaceuticals 25-YEAR LEGACY FUELING THERAPEUTIC INNOVATION

*Terms and Conditions: Offer applies only to prescriptions (1) that are subject to a private insurance co-pay requirement or (2) for which the patient has no insurance. Offer not valid for patients who are enrolled in a federal or state program that provides prescription benefits through retail or mail-order pharmacies, including Medicare Part D and Medicaid. Offer void where prohibited. Other restrictions apply. For full terms and conditions, please see the Qelbree Co-pay Card, or visit www.Qelbree.com.

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NEW ONCE-DAILY Qelbree

REASONS TO SWITCH UP THE APPROACH

1. First novel, nonscheduled medication option for ADHD in over a decade[1,2,9]
2. Once-daily, rapid- and extended-release, sprinkleable capsules for full-day exposure[1,6]
3. Proven efficacy in ADHD: demonstrated improvement in symptoms as early as week 1[1,6]
4. Proven safety and tolerability, with no evidence of abuse potential observed in clinical studies[1,6]

INDICATION

Qelbree is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in pediatric patients ages 6 to 17.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

In clinical studies, higher rates of suicidal thoughts and behaviors were reported in pediatric 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 Prescribing Information and Important Safety Information.

REFERENCES: 1. Qelbree [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc. **2.** Vyvanse [package insert]. Lexington, MA: Shire US. **3.** American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. Washington, DC: American Psychiatric Publishing; 2013. **4.** Castellanos FX, Proal E. Large-scale brain systems in ADHD: beyond the prefrontal-striatal model. *Trends Cogn Sci*. 2012;16(1):17-26. **5.** Centers for Disease Control and Prevention (CDC). Attention-deficit/hyperactivity disorder (ADHD)—Data and statistics about ADHD. CDC website. Accessed March 2, 2021. https://www.cdc.gov/ncbddd/adhd/data.html. **6.** Data on file, Supernus Pharmaceuticals. **7.** Subcommittee on Attention-Deficit/Hyperactivity Disorder, Steering Committee on Quality Improvement Management, Wolraich M, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. *Pediatrics*. 2019;144(4):e20192528. **8.** Yanagita T, Wakasa Y, Kiyohara H. Drug dependence potential of viloxazine hydrochloride tested in rhesus monkeys. *Pharmacol Biochem Behav*. 1980;12:155-161. **9.** US Food and Drug Administration. Summary review, NDA approval 22-037. September 2, 2009. Accessed March 12, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022037_intuniv_toc.cfm.

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