

Qelbree (Viloxazine) – Patient Information Handout

What is Qelbree?

Qelbree (viloxazine) is a non-stimulant prescription medication used to treat Attention-Deficit/Hyperactivity Disorder (ADHD) in adults and children aged 6 years and older. It works by affecting certain brain chemicals (norepinephrine and serotonin) that play a role in attention and impulse control.

Qelbree is not a controlled substance and is not a stimulant.

How Do I Take Qelbree?

- Take Qelbree **once daily**, in the morning or evening, with or without food.
- Swallow the capsule whole, **or** open it and sprinkle the contents onto a spoonful of applesauce or pudding. Swallow the mixture right away without chewing.
- Do not crush or chew the capsule contents.
- Your doctor will start you on a low dose and may gradually increase it.

Typical dosing:

- Children (ages 6-11): Starting dose 100 mg once daily; maximum 400 mg/day
- Adolescents (ages 12-17): Starting dose 200 mg once daily; maximum 400 mg/day
- Adults (ages 18+): Starting dose 200 mg once daily; maximum 600 mg/day

Do not change your dose or stop taking Qelbree without talking to your doctor.

What Should I Tell My Doctor Before Starting Qelbree?

Tell your doctor if you:

- Have or have had depression, suicidal thoughts, or bipolar disorder
 - Have heart problems, high blood pressure, or a fast heartbeat
 - Have liver or kidney problems
 - Are pregnant, planning to become pregnant, or breastfeeding
 - Are taking any other medications, vitamins, or supplements — especially:
 - **MAO inhibitors** (e.g., phenelzine, tranylcypromine, selegiline) — you must NOT take Qelbree with an MAOI or within 14 days of stopping one
 - Certain other medications that Qelbree can interact with, including some antidepressants, blood thinners, heart medications, theophylline, tizanidine, and caffeine
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What Are the Possible Side Effects?

Common side effects (these often improve over time):

- Sleepiness or fatigue
- Decreased appetite
- Nausea or vomiting
- Headache
- Trouble sleeping (insomnia)
- Irritability
- Dry mouth (more common in adults)
- Constipation (more common in adults)

Serious side effects — contact your doctor right away if you experience:

- New or worsening thoughts of suicide or self-harm
 - Unusual changes in mood or behavior, agitation, or aggression
 - Signs of mania: racing thoughts, greatly increased energy, reckless behavior, feeling extremely happy or irritable, talking more or faster than usual
 - Fast or pounding heartbeat, or a significant increase in blood pressure
 - Severe drowsiness that affects your daily activities
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Important Safety Warnings

⚠ **Suicidal Thoughts and Behaviors:** Qelbree may increase the risk of suicidal thoughts or behaviors, especially in children, teenagers, and young adults. Watch closely for new or worsening depression, anxiety, agitation, or unusual changes in behavior — particularly during the first few months of treatment or when the dose is changed. Contact your doctor immediately if these occur.

⚠ **Heart Rate and Blood Pressure:** Qelbree can raise your heart rate and blood pressure. Your doctor should check these before starting treatment, after dose changes, and regularly during treatment.

⚠ **Drowsiness:** Do not drive, operate heavy machinery, or do other dangerous activities until you know how Qelbree affects you.

What Should I Avoid While Taking Qelbree?

- Do not take MAO inhibitor medications while on Qelbree or within 14 days of stopping one.
- Be cautious with caffeine, as Qelbree can increase caffeine levels in your body.
- Avoid driving or hazardous activities if you feel drowsy or tired.

- Do not start or stop any medication without telling your doctor, as Qelbree can interact with many common drugs.
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Missed Dose

If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses at once.

Storage

Store at room temperature (68°F to 77°F / 20°C to 25°C). Keep in the original container and away from moisture. Keep out of reach of children.

When to Expect Results

Some patients notice improvement in ADHD symptoms within the first 1 to 2 weeks of treatment, though it may take 4 to 6 weeks to see the full benefit. Continue taking Qelbree as prescribed even if you do not notice immediate improvement.

Questions?

Talk to your doctor or pharmacist if you have any questions about Qelbree. To report side effects, call the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.