
VILOXAZINE XR (Qelbree) Fact Sheet

Bottom Line:

Like the first norepinephrine reuptake inhibitor for ADHD, atomoxetine, viloxazine has no abuse potential and is less likely than stimulants to cause insomnia, anxiety, or tics. However, it is generally less effective than stimulants and takes longer to work. It's unclear if it has any advantage, and unlike atomoxetine, there's no option for a cheaper generic.

FDA Indications:

ADHD (adults, children ≥ 6 years).

Off-Label Uses:

Treatment-resistant depression.

Dosage Forms:

ER capsules: 100 mg, 150 mg, 200 mg.

Dosage Guidance:

- Children 6–11: Start 100 mg QD, \uparrow by 100 mg/day at weekly intervals to max 400 mg QD.
- Children 12–17: Start 200 mg QD, \uparrow by 200 mg after one week to max 400 mg QD.
- Adults: Start 200 mg QD, \uparrow by 200 mg/day at weekly intervals to max 600 mg QD.

Monitoring: Baseline renal function.

Cost: \$\$\$\$

Side Effects:

- Most common: Somnolence, decreased appetite, fatigue, nausea, vomiting, insomnia, irritability.
- Serious but rare: Class warning for suicidal ideation in children and teens. Mania reported. May increase pulse and BP.
- Pregnancy/breastfeeding: Not recommended due to lack of human data and concerning animal data..

Mechanism, Pharmacokinetics, and Drug Interactions:

- Selective norepinephrine reuptake inhibitor (NRI).
- Metabolized primarily via CYP2D6, UGT1A9, UGTB15; $t_{1/2}$: 7 hours.
- Avoid use with MAOIs. Strong 1A2 inhibitor; exercise caution with 1A2 substrates with narrow therapeutic index (eg, clozapine, duloxetine, ramelteon, tasimelteon, theophylline, tizanidine) as combination may increase side effects of substrate.

Clinical Pearls:

- ER capsules, so do not cut, crush, or chew; can open and sprinkle contents in applesauce or pudding.
- Adjust dose in severe renal impairment (eGFR < 30 mL/min); max 200 mg/day.
- Data from one of four studies suggest viloxazine may work a bit faster than atomoxetine (week one vs week three), but this finding is not based on head-to-head data and it's hard to know whether it is clinically significant.

Fun Fact:

Viloxazine has been studied for various indications since the 1970s and originally received an FDA orphan drug designation for narcolepsy.