

MEDICATION GUIDE
QELBREE® (Kel' bree)
(viloxazine extended-release capsules)
for oral use

What is the most important information I should know about QELBREE?

QELBREE can cause serious side effects, including:

- **Increased risk of suicidal thoughts or actions.** QELBREE may increase suicidal thoughts or actions in children and adults with attention deficit hyperactivity disorder (ADHD), **especially within the first few months of treatment or when the dose is changed.**

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings or if you or your child develops suicidal thoughts or actions. This is very important when QELBREE treatment is started or when the dose is changed.
- Call your healthcare provider right away if you or your child has any new or sudden changes in mood, behavior, thoughts, or feelings, or if you or your child develops suicidal thoughts or actions.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call your healthcare provider or get emergency help right away if you or your child has any of the following symptoms, especially if they are new, worse, or worry you:

- | | |
|---|---|
| ○ attempts to commit suicide | ○ thoughts about suicide or dying |
| ○ new or worse depression | ○ new or worse anxiety |
| ○ feeling very agitated or restless | ○ panic attacks |
| ○ trouble sleeping (insomnia) | ○ new or worse irritability |
| ○ acting aggressive, being angry, or violent | ○ acting on dangerous impulses |
| ○ an extreme increase in activity and talking (mania) | ○ other unusual changes in behavior or mood |

See **“What are the possible side effects of QELBREE?”** for more information about side effects.

What is QELBREE?

QELBREE is a prescription medicine used to treat attention deficit hyperactivity disorder (ADHD) in adults and children 6 years of age and older.

It is not known if QELBREE is safe and effective in children less than 6 years of age.

Do not take QELBREE if you or your child:

- takes a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you or your child takes an MAOI.
- stopped taking an MAOI in the last 14 days.
- takes alosetron, duloxetine, ramelteon, tasimelteon, tizanidine, or theophylline.

Before taking QELBREE, tell your healthcare provider about all your or your child’s medical conditions, including if you or your child:

- have, or have a family history of, suicide, bipolar disorder, depression, mania or hypomania
- have blood pressure or heart rate problems
- have severe kidney problems. Your healthcare provider may lower the dose of QELBREE.
- are pregnant or plan to become pregnant. QELBREE may cause harm to the mother when taken during pregnancy. You and your healthcare provider will decide if QELBREE should be taken during pregnancy.
 - Tell your healthcare provider right away if you or your child become pregnant or think they are pregnant during treatment with QELBREE.
 - There is a pregnancy registry for females who are exposed to QELBREE during pregnancy. The purpose of the registry is to collect information about the health of females exposed to QELBREE and their baby. If you become pregnant while taking QELBREE, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications by calling 1-866-961-2388 or go to www.womensmentalhealth.org/preg.
- are breastfeeding or plan to breastfeed. It is not known if QELBREE passes into breastmilk. Talk to your healthcare provider about the best way to feed the baby during treatment with QELBREE.

Tell your healthcare provider about all the medicines you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

QELBREE and other medicines may affect each other causing possible serious side effects.

Your healthcare provider will decide if QELBREE can be taken with other medicines.

Especially tell your healthcare provider if you or your child take:

- MAOIs
- alosetron
- duloxetine
- ramielteon
- tasimelteon
- tizanidine
- theophylline

Know the medicines you or your child takes. Keep a list of them and show it to your healthcare provider and pharmacist when you or your child get a new medicine.

Do not start any new medicine during treatment with QELBREE without first talking to your healthcare provider.

How should I take QELBREE?

- Take QELBREE exactly as your healthcare provider tells you to take it.
- Take QELBREE 1 time each day with or without food.
- Swallow QELBREE capsules whole. Do not cut, crush, or chew the capsules.
- If QELBREE capsules cannot be swallowed whole, the capsule may be opened and the entire contents sprinkled onto a teaspoonful or tablespoonful of pudding or applesauce.
- Swallow all the food mixture right away, **without chewing**, or within 15 minutes of mixing for pudding, or within 2 hours of mixing for applesauce.
 - **Do not** chew the food mixture.
 - **Do not** store food mixture.
- Talk to your healthcare provider about what you should do if you or your child misses a dose.
- If you or your child take too much QELBREE or overdoses, call your poison control center at 1-800-222-1222 right away, or go to the nearest emergency room.

What should I avoid while taking QELBREE?

Do not drive or operate heavy machinery until you know how QELBREE will affect you. QELBREE may cause you to feel sleepy or tired.

What are the possible side effects of QELBREE?

QELBREE can cause serious side effects, including:

- See “**What is the most important information I should know about QELBREE?**”
- **Increased blood pressure and heart rate.** Your healthcare provider should check you or your child’s blood pressure and heart rate before starting and during treatment with QELBREE.
- **Manic episodes.** Manic episodes may happen in people with bipolar disorder who take QELBREE. Symptoms may include:
 - greatly increased energy
 - racing thoughts
 - unusually grand ideas
 - talking more or faster than usual
 - severe trouble sleeping
 - reckless behavior
 - excessive happiness or irritability
- **Sleepiness and tiredness.** See “**What should I avoid while taking QELBREE?**”

The most common side effects of QELBREE in children 6 to 17 years of age include:

- sleepiness
- tiredness
- vomiting
- irritability
- decreased appetite
- nausea
- trouble sleeping

The most common side effects of QELBREE in adults include:

- insomnia
- sleepiness
- nausea
- dry mouth
- headache
- tiredness
- decreased appetite
- constipation

Effects on weight. Your healthcare provider should check your or your child's weight before starting and during treatment with **QELBREE**.

These are not all of the possible side effects of QELBREE.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store QELBREE?

- Store QELBREE capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep QELBREE and all medicines out of the reach of children.**

General Information about the safe and effective use of QELBREE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not take QELBREE for a condition for which it was not prescribed. Do not give QELBREE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about QELBREE that is written for health professionals.

What are the ingredients in QELBREE?

Active ingredient: viloxazine

Inactive ingredients: ammonium hydroxide, black iron oxide, butyl alcohol, corn starch, ethylcellulose, FD&C Blue #1, FD&C Red #28, FD&C Yellow #5, FD&C Yellow #6, FD&C Yellow #10, gelatin, hypromellose, isopropyl alcohol, lactose monohydrate, medium chain triglycerides, oleic acid, polyethylene glycol, potassium hydroxide, propylene glycol, shellac, strong ammonia solution, sucrose, talc, triacetin, titanium dioxide.

Manufactured by: Catalent Pharma Solutions, LLC, 1100 Enterprise Drive, Winchester KY 40391, USA

Distributed by: Supernus Pharmaceuticals, Inc., Rockville, MD USA 20850

© Supernus Pharmaceuticals Inc.

For more information, go to www.supernus.com or call 1-866-398-0833.

RA-QBE-MGVX-YYYYMM