



Talk To Your Doctor About Migraine Prevention

(NAPSA)—A migraine headache can be debilitating and sometimes hit like a runaway freight train, but did you know that in some cases it's preventable? Unfortunately, migraine preventive therapy is severely underutilized. Nearly 40 percent of people who suffer from migraine could benefit from preventive treatment, but only a small percentage receive this type of therapy.¹

Migraine prevention is just a conversation away. Here's some information about migraine and preventive treatment options to help you start a dialogue with your doctor.

What causes migraine and can it be prevented?

Just about everyone has headaches, but contrary to popular belief, migraine is not just a bad headache.² In fact, the World Health Organization places migraine as one of the 10 most disabling illnesses on the planet.³ Doctors aren't exactly sure what causes migraine headaches, but they think imbalances in certain brain chemicals may play a role, along with genetics and other factors including:⁴

- **Physical and environmental elements.** Emotional stress (one of the most common migraine triggers); consuming salty, processed foods and alcohol and caffeine; skipping meals; sensory overload; changes in sleep pattern; physical



Doctors have new ways to prevent migraine headaches.

- strain; and changes in weather patterns.
- **Genes.** A family history of migraine increases the likelihood of having migraines.
- **Age.** Migraine headaches can occur at any point in life, but the first one usually happens during the teenage years. Migraines tend to peak in the thirties and are less severe later in life.
- **Gender.** Women experience migraine more than men.
- **Hormonal changes.** Birth control pills and hormone replacement therapy can make migraine symptoms worse for some women but better for others.

Knowing your pattern of getting a migraine headache, and learning what triggers to avoid, are helpful prevention techniques. For those with frequent migraines who aren't able to avoid or effectively treat a migraine headache after it has started, migraine prevention therapy may be an answer.

What are some migraine prevention treatment options?

For patients with frequent migraine attacks (1-2 per week or more), doctors recommend preventive therapy.⁵ Topiramate is the most commonly prescribed migraine preventive due to a sizable body of evidence demonstrating its ability to improve outcomes in migraine patients in terms of reduced disability and improved quality of life.⁶ The American Academy of Neurology and the American Headache Society have given topiramate a "top tier" rating for migraine prevention.⁷

The Food & Drug Administration (FDA) has approved Qudexy® XR (topiramate) extended-release capsules, for use in the prevention of migraine headaches in adults and adolescents 12 years of age and older. Qudexy XR is taken once daily by mouth.

In addition, three injectable anti-calcitonin gene-related peptide (CGRP) therapies, indicated for the preventive treatment of migraine in adults, were recently approved by the FDA.

With all of the treatments available for the prevention of migraine, it's important to talk to your doctor and discuss options that can be tailored to your individual needs.

For more information about migraine prevention and Qudexy® XR, talk to your doctor or visit www.QudexyXR.com.

WHAT IMPORTANT SAFETY INFORMATION SHOULD I KNOW?

Qudexy® XR should not be used in patients with metabolic acidosis who are also taking a medicine called metformin (e.g., Glucophage®).

Qudexy XR can cause serious side effects, including:

- **Serious eye problems**, which may include blurred or sudden decrease in vision, eye pain and redness or a blockage of fluid that may cause increased pressure in the eye (secondary angle closure glaucoma). If left untreated, this can lead to permanent vision loss.
- **Decreased sweating and fever.** People, especially children, should be watched for signs of decreased sweating and fever, especially in hot temperatures. Some people may need to be hospitalized for this condition.
- **Increased acid level in the blood (metabolic acidosis).** This may or may not cause symptoms. Symptoms may include feeling tired, decreased appetite, change in heartbeat, or trouble thinking clearly. If left untreated, metabolic acidosis can cause brittle or soft bones (osteoporosis, osteomalacia, osteopenia), kidney stones, can slow the rate of growth in children, and may possibly harm the unborn child of pregnant patients.
- **High blood ammonia levels.** High ammonia in the blood can affect mental activities, slow alertness and cause tiredness or vomiting. This can also happen when Qudexy XR is taken with a medicine called valproic acid (e.g., Depakene® and Depakote®).
- **Kidney stones.** Drink plenty of fluids when taking Qudexy XR to decrease your chances of getting kidney stones.
- **Low body temperature.** Taking Qudexy XR when you are also taking valproic acid may cause a drop in body temperature to less than 95°F, tiredness, confusion, or coma.
- **Effects on thinking and alertness.** Qudexy XR may affect how you think, and can cause confusion, problems with concentration, attention, memory, or speech. Qudexy XR may cause depression or mood problems, tiredness, and sleepiness.
- **Dizziness or loss of muscle coordination.**

Call your healthcare provider right away if you have any of the above symptoms.

Like other antiepileptic drugs, Qudexy XR may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Before taking Qudexy XR, tell your healthcare provider if you have or have had depression, mood problems, or suicidal thoughts or behavior. Call a healthcare provider right away if you have thoughts about suicide or dying; attempt to commit suicide; have new or worsening depression or anxiety; feel agitated or restless; experience panic attacks; have trouble sleeping (insomnia), new or worsening irritability; feel or act aggressive, angry, or violent; act on dangerous impulses; experience an extreme increase in activity and talking (mania); or other unusual changes in your behavior or mood.

Qudexy XR can harm your unborn baby. All women of childbearing age should talk to their healthcare provider about possible alternative treatments. If you take Qudexy XR during pregnancy, your baby has a higher risk for birth defects called cleft lip and cleft palate. These defects can begin early in pregnancy, even before you know you are pregnant. Also, if you take Qudexy XR during pregnancy, your baby may be smaller than expected at birth; the long-term effects of this are not known. If the decision is made to use Qudexy XR, you should use effective birth control (contraception). **Tell your healthcare provider right away if you become, or plan to become pregnant while taking Qudexy XR.**

The most common side effects of Qudexy XR include: tingling of the arms and legs (paresthesia), not feeling hungry, weight loss, nervousness, nausea, speech problems, tiredness, dizziness, sleepiness/drowsiness, a change in the way foods taste, upper respiratory tract infection, slow reactions, difficulty with memory, fever, abnormal vision, diarrhea, and pain in the abdomen. These are not all the possible side effects of Qudexy XR. For more information, ask your healthcare provider or pharmacist.

Before taking Qudexy XR, tell your healthcare provider about all of your medical conditions, including if you: have had depression, mood problems, or suicidal thoughts or behavior; have kidney problems, kidney stones, or are getting kidney dialysis; have a history of metabolic acidosis (too much acid in the blood); have liver problems; have weak, brittle or soft bones (osteomalacia, osteoporosis, osteopenia, or decreased bone density); have lung or breathing problems; have eye problems, especially glaucoma; have diarrhea; have a growth problem; are on a diet high in fat and low in carbohydrates, which is called a ketogenic diet; are having surgery; are pregnant or planning to become pregnant; or if you are breastfeeding. The medicine in Qudexy XR (topiramate) passes into your breast milk. It is not known if the medicine, topiramate, that passes into breast milk can harm your baby. Talk with your healthcare provider about the best way to feed your baby if you take Qudexy XR.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take metformin (e.g., Glucophage); valproic acid (e.g., Depakene or Depakote); any medicines that impair or decrease your thinking, concentration, or muscle coordination; birth control pills (Qudexy XR may make birth control pills less effective); medicines used to prevent seizures; or any other carbonic anhydrase inhibitors (e.g., zonisamide, acetazolamide, or dichlorophenamide).

Do not stop Qudexy XR without first talking to a healthcare provider. If you have epilepsy and you stop taking Qudexy XR suddenly, you may have seizures that do not stop. Your healthcare provider will tell you how to stop taking Qudexy XR slowly.

Do not drink alcohol while taking Qudexy XR. Qudexy XR and alcohol can cause serious side effects such as severe sleepiness and dizziness and an increase in seizures.

Do not drive a car, swim, climb, or operate heavy machinery until you know how Qudexy XR affects you. Qudexy XR can slow your thinking and motor skills, and may affect vision. Even when taking Qudexy XR, some patients with epilepsy will continue to have unpredictable seizures.

WHAT IS QUDEXY XR?

Qudexy® XR (topiramate) Extended-Release Capsules is a prescription medicine used:

- To prevent migraine headaches in adults and adolescents 12 years and older.
- To treat certain types of seizures (partial-onset seizures and primary generalized tonic-clonic seizures) in adults and children 2 years and older.
- With other medicines to treat certain types of seizures (partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome) in adults and children 2 years and older.

This is the most important information to know about Qudexy XR, but is not comprehensive. For more information, talk to your healthcare provider and read the Medication Guide for Qudexy XR. You can also visit www.upsheer-smith.com or call 1-888-650-3789.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Qudexy is a registered trademark of Upsher-Smith Laboratories, LLC.

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1. National Headache Foundation. Migraine Prevention Therapy: What's in the Pipeline? Available at <https://headaches.org/2017/03/13/migraine-preventive-therapy-whats-pipeline/>. Accessed September 20, 2018.
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3. American Migraine Foundation. Available at <https://americanmigrainefoundation.org/living-with-migraine/>. Accessed September 12, 2018.
4. WebMD. Available at <https://www.webmd.com/migraines-headaches/migraines-causes#1>. Accessed September 12, 2018.
5. American Headache Society. Available at https://americanheadachesociety.org/wp-content/uploads/2018/05/Alan_Rapoport_-_Migraine_Prevention_Medications.pdf. Accessed September 12, 2018.
6. Silberstein SD. Topiramate in Migraine Prevention: A 2016 Perspective. Headache. 2017 Jan;57(1):165-178.
7. Silberstein SD, Holland S, Freitag F, Dodick DW, Argoff C, Ashman E. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. 2012;78(17):1337-1345.