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**FOR IMMEDIATE RELEASE**

## **UPSHER-SMITH LAUNCHES “IT’S THAT SIMPLE” PROGRAM FOR QUDEXY® XR (TOPIRAMATE) EXTENDED-RELEASE CAPSULES**

### **New Program Simplifies Access and Provides \$0 Co-Pay for Eligible Patients**

Maple Grove, MN – September 8, 2016 – [Upsher-Smith Laboratories, Inc.](#) (Upsher-Smith), today announced the availability of the [“It’s That Simple” program](#) - a new savings and support program that makes it easier for physicians to prescribe [Qudexy® XR \(topiramate\) extended-release capsules](#) and offers a \$0 co-pay for eligible patients. Qudexy® XR is a once-daily, broad-spectrum antiepileptic drug. The program includes:

- **\$0 Co-Pay Offer for Eligible Patients:** The offer covers \$200/per prescription for a maximum annual savings of \$2,400 and is available at pharmacies nationwide through an e-voucher or for download at [QudexyXR.com](#).
- **30-day Samples:** Patients prescribed Qudexy® XR can get started immediately with a free 30-day sample, even when a prior authorization is required.
- **Qudexy® XR Support Line:** The single source for all Qudexy® XR questions that offers personal assistance with benefit verification and prior authorizations.
- **Prior Authorization Assistance:** A pharmacy-based program that offers an efficient way to electronically complete prior authorization requests for nearly all health plans.

In addition to savings and support benefits, patients and physicians have more options with Qudexy® XR. Qudexy® XR is the only 100% extended-release bead formulation of topiramate, providing smooth topiramate levels over a 24-hour period with once-daily dosing. All strengths of Qudexy® XR (25 mg, 50 mg, 100 mg, 150 mg, and 200 mg capsules) are FDA-approved for administration as an intact capsule or via a sprinkle method (i.e. opening the capsule and sprinkling its contents onto a small amount of soft food).

The Qudexy® XR “It’s That Simple” program’s \$0 co-pay offer is available only to commercially-insured and cash-paying patients. Patients covered by Medicaid, Medicare,

TriCare or other federal or state programs are not eligible. Samples and the Support Line are available to all patients. For more information, visit [QudexyXR.com](http://QudexyXR.com).

“Having simplified access to quality, affordable medications is critical to all patients, including those with epilepsy,” said Rusty Field, President, Upsher-Smith. “The ‘It’s That Simple’ program for Qudexy® XR offers patients affordable access and enhanced support while enabling healthcare professionals to prescribe the product with greater ease and efficiency. We are pleased to offer more options to patients with epilepsy and to their physicians.”

Patients and healthcare practitioners with specific questions about Qudexy® XR or the [“It’s That Simple” program](http://QudexyXR.com) can visit [QudexyXR.com](http://QudexyXR.com) or call the Qudexy® XR support line at 1-855-282-4887.

## WHAT IS QUDEXY XR?

Qudexy® XR (topiramate) Extended-Release Capsules is a prescription medicine used to treat certain types of seizures (partial-onset seizures and primary generalized tonic-clonic seizures) and 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.

## WHAT IMPORTANT SAFETY INFORMATION SHOULD I KNOW ABOUT QUDEXY XR?

**Qudexy® XR should not be taken by** patients with metabolic acidosis who are also taking a medicine called metformin.

## What should I tell my health care provider BEFORE starting Qudexy XR?

**Tell your health care provider if you take** any medicines that impair or decrease thinking, concentration, or muscle coordination; medicines used to prevent seizures; any other carbonic anhydrase inhibitors; or birth control pills. Qudexy XR may make birth control pills less effective.

## Qudexy XR can cause serious side effects, including:

- **Serious eye problems**, including blurred or sudden decrease in vision and increased pressure in the eye, which can lead to permanent vision loss.
- **Decreased sweating and fever**, especially in hot weather which may result in hospitalization; children are especially susceptible to these effects.
- **Increased acid level in the blood (metabolic acidosis)**, which may lead to brittle or soft bones (osteoporosis, osteomalacia, osteopenia), kidney stones, slowed rate of growth in children and fetal harm. Metabolic acidosis may or may not cause symptoms. Symptoms may include feeling tired, decreased appetite, change in heartbeat, or trouble thinking clearly.
- **High ammonia level in the blood**, which can affect mental activities, slow alertness and cause tiredness and vomiting. This can also happen when Qudexy XR is taken with a medicine called valproic acid.
- **Kidney stone formation**, which may be reduced by increasing fluid intake while taking Qudexy XR.

- **Low body temperature.** Taking Qudexy XR while taking valproic acid may cause a drop in body temperature to less than 95°F with associated symptoms of tiredness, confusion, or coma.
- **Effects on thinking and alertness.** Qudexy XR may affect thinking, and cause confusion and problems with concentration, attention, memory, or speech. Qudexy XR may cause depression or mood problems, tiredness, and sleepiness.
- **Dizziness or loss of muscle coordination.**
- **Fetal harm.** Taking Qudexy XR while pregnant increases the risk of cleft lip and cleft palate for the fetus. Alternative treatment or effective birth control should be used. Discuss with your health care provider.
- **Suicidal thoughts and actions.** Like other antiepileptic drugs, Qudexy XR may cause suicidal thoughts and actions in a very small number of people, about 1 in 500. Tell your health care provider right away if you experience these effects, or any symptoms of depression or mood changes.

**Tell your health care provider right away if you have any of the above symptoms, are planning to become pregnant, or if you 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, speech problems, tiredness, dizziness, sleepiness/drowsiness, slow reactions, difficulty with memory, fever, and abnormal vision. These are not all the possible side effects of Qudexy XR. For more information, ask your health care provider or pharmacist.

**Before taking Qudexy XR, tell your health care 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 plan 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 to your health care provider about the best way to feed your baby if you take Qudexy XR.

**Qudexy XR should not be taken while drinking alcohol,** as this can cause serious side effects such as severe sleepiness, dizziness, and an increase in seizures.

**Patients taking Qudexy XR should not drive, swim, climb, or operate heavy machinery until it is known how Qudexy XR affects them.** Qudexy XR can slow thinking and motor skills and may affect vision. Some patients with epilepsy taking Qudexy XR will continue to have unpredictable seizures.

**Do not stop Qudexy XR without first talking to a health care provider.** If you have epilepsy and you stop taking Qudexy XR suddenly, you may have seizures that do not stop.

**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.upsher-smith.com](http://www.upsher-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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

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

### **About Upsher-Smith**

Upsher-Smith Laboratories, Inc., founded in 1919, is a growing, fully integrated pharmaceutical company dedicated to its mission of delivering high-value, high-quality therapies and solutions which measurably improve individuals' lives. As a family-owned pharmaceutical company, we are able to adapt and thrive in a dynamic healthcare environment. Our world is constantly evolving, and we are continually adapting to the ever-changing needs of patients, physicians, pharmacists, and healthcare organizations. Where there is a need, we will work to deliver solutions that simplify access to treatment, deliver better health outcomes, and enhance life. Upsher-Smith has a particular focus on developing therapies for people living with central nervous system (CNS) conditions, such as seizure disorders. For more information, visit [www.upsher-smith.com](http://www.upsher-smith.com).

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