

**UPSHER-SMITH**

Partners in Health Since 1919

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**FOR IMMEDIATE RELEASE**

**UPSHER-SMITH SHOWCASES ACCESS PATHWAYS™ PROGRAM AT  
71<sup>ST</sup> ANNUAL MEETING OF THE AMERICAN EPILEPSY SOCIETY**

Maple Grove, MN – November 29, 2017 – [Upsher-Smith Laboratories, LLC](#) (Upsher-Smith) today announced that it will be exhibiting at the 71<sup>st</sup> Annual Meeting of the American Epilepsy Society (AES), December 1-5, 2017, in Washington, DC. Meeting attendees are encouraged to visit booth #1126 to learn more about Upsher-Smith's Access Pathways™ Program and the latest [Qudexy® XR \(topiramate\) extended-release capsules](#) updates. Qudexy® XR is indicated for treating certain types of seizures and for use in the prevention of migraine headache.

The Access Pathways™ Program is designed to reduce the barriers associated with prescribing the product and provides healthcare professionals with the tools necessary to help their patients *Start, Stay and Save* on Qudexy® XR therapy. Please visit [hcp.QudexyXR.com](http://hcp.QudexyXR.com) to access an informational video, a guide on how to get started and a patient enrollment form.

The Access Pathways™ Program includes:

- Benefit verification
- Prior authorization support†
- E-voucher pharmacy finder
- Pharmacy stocking assistance
- \$0 Co-pay offer\*
- Qudexy® XR “Pay No More Than” option

To learn more about Upsher-Smith's Access Pathways™ Program, please visit [hcp.QudexyXR.com](http://hcp.QudexyXR.com) or call 1-855-282-4887 Monday-Friday from 8:00 a.m. – 7:00 p.m. (EST).

## **WHAT IS QUDEXY XR?**

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

- **Migraine:** To prevent migraine headaches in adults and adolescents 12 years and older.
- **Monotherapy Epilepsy:** Initial monotherapy to treat certain types of seizures (partial-onset seizures and primary generalized tonic-clonic seizures) in adults and children 2 years and older.

- **Adjunctive Epilepsy:** Adjunctive therapy 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 healthcare provider BEFORE starting Qudexy XR?**

**Tell your healthcare 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 fetus risk of cleft lip and/or cleft palate and of being small for gestational age. Alternative treatment or effective birth control should be used. Discuss with your healthcare 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 healthcare provider right away if you experience these effects, or any symptoms of depression or mood changes.

**Tell your healthcare 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, 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 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 healthcare 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 healthcare 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) for the full [Prescribing Information](#) 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 and Access Pathways are trademarks of Upsher-Smith Laboratories, LLC.

### **About Upsher-Smith**

Upsher-Smith Laboratories, LLC is a trusted U.S. pharmaceutical company that has strived to deliver quality, affordable generic medications for nearly a century. In June 2017, Upsher-Smith was acquired by Sawai Pharmaceutical Co., Ltd., a large publicly traded generics company in Japan that had been seeking entry into the U.S. market. Upsher-Smith and Sawai

share a strikingly similar family history and hold many of the same cherished goals and values—most importantly, the philosophy of always putting patients first.

Upsher-Smith will continue to do those things it does best, which is provide a consistent supply of quality, affordable medications and invest in its historically strong industry relationships. Ultimately, Upsher-Smith believes the acquisition by Sawai represents a tremendous opportunity to leverage each other for growth worldwide and embark together on an exciting new chapter in generics. For more information, visit [www.upsher-smith.com](http://www.upsher-smith.com).

† For FDA-approved indications only.

\*Eligible patients pay \$0. Covers up to a maximum of \$200/prescription. Maximum annual savings of \$2,400. Medicare, Medicaid, and other state and federal health care program patients are not eligible.

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