# UPSHER-SMITH

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### FOR IMMEDIATE RELEASE

## UPSHER-SMITH UNVEILS EDUCATIONAL RESOURCES AND SUPPORT TOOLS FOR MIGRAINE PATIENTS

Maple Grove, MN – May 3, 2019 – Upsher-Smith Laboratories, LLC (Upsher-Smith) today announced the launch of its newly redesigned website for Qudexy<sup>®</sup> XR (topiramate) Extended-Release Capsules. The enhanced website offers support tools and educational resources for those living with migraine and seeking information about preventative treatment. The Company has also



introduced a new Facebook page that is a source of information and support for migraine sufferers. Qudexy<sup>®</sup> XR is indicated for use in the prevention of migraine headache in adults and adolescents 12 years of age and older and is also indicated to treat certain types of seizures in patients 2 years and older. Qudexy<sup>®</sup> XR is taken once-daily by mouth.

Key features of the new patient-centered website include: information about migraine disease; links to migraine resources; an opt-in patient email series; tips for preventing migraine; and patient savings on Qudexy<sup>®</sup> XR.

"Managing migraines is often complex, and starting a new medication routine can be challenging," said Rusty Field, President and CEO, Upsher-Smith. "Our new website was designed with that in mind, offering patients easy access to migraine support tools, information about migraine prevention treatment options and ways eligible patients can start, stay and save on Qudexy<sup>®</sup> XR."

Enhancements to the Qudexy<sup>®</sup> XR website include:

- **Patient Email Series:** Patients can sign up to receive helpful information about what to expect while taking Qudexy<sup>®</sup> XR and other migraine-related topics.
- Migraine Support: Patients can learn about the causes, symptoms and triggers of migraine; how migraine may be diagnosed; proactive steps to reduce migraine; and links to additional migraine resources.

- Patient Savings: Patients can easily access information about Access Pathways<sup>®</sup>, a dedicated savings and support team that offers co-pay assistance and administrative support to help patients *Start, Stay and Save* on Qudexy<sup>®</sup> XR therapy. Patients can present the Platinum Pass<sup>™</sup> savings card to their pharmacist for instant savings that last all year (365 days of therapy) and is renewable annually. Commercially insured patients pay \$0 per prescription regardless of coverage\* and no activation is required prior to going to a preferred pharmacy.
- Authorized Generic: Topiramate Extended-Release Capsules from Upsher-Smith are the authorized generic of Qudexy<sup>®</sup> XR. It's the same medication as Qudexy<sup>®</sup> XR, just with a different name. The Access Pathways<sup>®</sup> Program is available for both Qudexy<sup>®</sup> XR and Topiramate Extended-Release Capsules.

## About Topiramate

Topiramate is the most commonly prescribed migraine preventative 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.<sup>1</sup> The American Academy of Neurology and the American Headache Society have given topiramate a "top tier" (Level A: established efficacy) rating for migraine prevention.<sup>2</sup> For patients with frequent migraine attacks (1-2 per week or more), doctors may recommend preventative therapy.<sup>3</sup>

## 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<sup>®</sup>).

### **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<sup>®</sup> and Depakote<sup>®</sup>).
- 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 dichlorphenamide).

**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<sup>®</sup> 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 tonicclonic 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.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, or call 1-800-FDA-1088.

### **About Upsher-Smith**

Upsher-Smith Laboratories, LLC is a trusted U.S. pharmaceutical company that strives to improve the health and lives of patients through an unwavering commitment to high-quality products and sustainable growth. Since 1919, it has brought generics and brands to a wide array of customers backed by an attentive level of service, strong industry relationships, and dedication to uninterrupted supply.

As Upsher-Smith celebrates its 100-year anniversary, the company enters a new ambitious era that has been accelerated by its 2017 acquisition by Sawai Pharmaceutical Co., Ltd. Upsher-Smith and Sawai plan to leverage each other for growth worldwide and embark on an exciting new chapter as they seek to deliver the best value for their stakeholders, and most importantly, Do More Good<sup>™</sup> for the patients they serve. For more information, visit

### www.upsher-smith.com.

Qudexy, Access Pathways, Platinum Pass and Do More Good are trademarks of Upsher-Smith Laboratories, LLC. All other marks are the property of their respective owners.

\*Restrictions apply. Medicare, Medicaid, and other state and federal health care program patients are not eligible.

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#### References

- 1. Silberstein, S.D. (2017), Topiramate in Migraine Prevention: A 2016 Perspective. Headache: The Journal of Head and Face Pain, 57: 165-178. doi: 10.1111/head.12997.
- 2. Headache. 2019 Jan;59(1):1-18. doi:10.1111/head. 13456. Epub 2018 Dec 10. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. American Headache Society.
- 3. American Headache Society. Available at https://americanheadachesociety.org/wpcontent/uploads/2018/05/Alan\_Rapoport\_-\_Migraine\_Prevention\_Medications.pdf. Accessed February 19, 2019.

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