What is the most important information I should know about QUDEXY XR? QUDEXY XR may cause eye problems. Some eye problems include:

• any sudden decrease in vision with or without eye pain and redness,
• a blockage of fluid in the eye causing increased pressure in the eye (secondary angle closure glaucoma).

These problems may lead to permanent vision loss if not treated. You should call your healthcare provider right away if you have any new eye symptoms, including any new problems with your vision.

QUDEXY XR may cause decreased sweating and increased body temperature (heat exhaustion). People, especially children, should be watched for any signs of decreased sweating and fever, especially when they are exposed to hot temperatures. Some people may need to be hospitalized for heat exhaustion.

If you have a fever, a fluid that does not go down, or decreased sweating develops, call your healthcare provider right away.

QUDEXY XR can increase the level of acid in your blood (metabolic acidosis). If left untreated, metabolic acidosis can cause brittle or soft bones (osteomalacia, osteoporosis, osteopenia, or decreased bone density), can slow the rate of growth in children, and can harm your baby if you are pregnant. Metabolic acidosis can happen with or without symptoms. Sometimes people with metabolic acidosis will:

• feel tired
• not feel hungry (loss of appetite)
• have trouble breathing faster
• have trouble thinking clearly

Your healthcare provider should do a blood test to measure the level of acid in your blood before and during your treatment with QUDEXY XR.

If you are pregnant, you should talk to your healthcare provider about whether you have metabolic acidosis.

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

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

• thoughts about suicide or dying
• acting very agitated or restless
• aggressive or violent behavior
• trouble sleeping (insomnia)
• new or worse anxiety
• new or worse depression
• thoughts about suicide or dying
• behavior or mood changes

Call your healthcare provider at once if you have any other unusual changes in behavior or mood.

What is the most important information I should know about QUDEXY XR? QUDEXY XR is a prescription medicine used:

• to treat certain types of seizures (partial-onset seizures and primary generalized tonic-clonic seizures) in adults and children 2 years of age 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 of age and older.

• to prevent migraine headaches in adults and adolescents 12 years of age and older.

Tell your healthcare provider if you are planning to become pregnant. You should talk to your healthcare provider about the best kind of birth control to use while you are taking QUDEXY XR.

Before taking QUDEXY XR, tell your healthcare provider about all of your medical conditions, including if you:

• have or have had depression, mood problems, or suicidal thoughts or actions
• have mental health problems
• are taking or have taken a medicine for depression or other mental health problem
• have liver problems
• have kidney problems, kidney stones or are getting kidney dialysis
• are on a diet high in fat and low in carbohydrates, which is called a ketogenic diet
• have kidney problems, kidney stones or are getting kidney dialysis
• have or have had diabetes
• have a growth problem
• are on a diet high in fat and low in carbohydrates, which is called a ketogenic diet
• are having surgery
• have or have had kidney problems
• have weak, brittle or soft bones (osteomalacia, osteoporosis, osteopenia, or decreased bone density)
• have diarrhea
• are taking birth control pills. QUDEXY XR may make your birth control pills less effective. Tell your healthcare provider if your menstrual bleeding changes while you are taking birth control pills and QUDEXY XR.

What should I tell my healthcare provider before taking QUDEXY XR? Before taking QUDEXY XR, your healthcare provider will tell you how to stop taking QUDEXY XR slowly.

Tell your healthcare provider about all of the medicines you take. This includes prescription, over-the-counter, vitamins, and herbal products. QUDEXY XR and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

• antidepressants (such as DEPAKENE® or DEPAKOTE®)
• lithium (such as LITHIUM CARBONATE, or CARBOLITHIUM®)
• medicines that impair or decrease your thinking, concentration, or muscle coordination
• birth control pills. QUDEXY XR may make your birth control pills less effective.
• any medicines that impair or decrease your thinking, concentration, or muscle coordination
• any medicines that make you sleepy or stop you from keeping busy

Tell your healthcare provider if your menstrual bleeding changes while you are taking birth control pills and QUDEXY XR.

Ask your healthcare provider if you are not sure if your medicine is listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine. Do not take a new medicine without talking with your healthcare provider.

How should I take QUDEXY XR? Take QUDEXY XR exactly as your healthcare provider tells you to.

Your healthcare provider may change your dose without talking to your healthcare provider.

• QUDEXY XR capsules may be swallowed whole or, if you cannot swallow the capsule whole, you may carefully open the capsule and, if possible, get the soft, moist content of the capsule and put it on a soft food to help it swallow.

• Swallow the food and medicine mixture right away. Do not store the food and medicine mixture to use later.

• Do not crush or chew QUDEXY XR capsules or tablets.

• Drink plenty fluids during the day. This may help prevent kidney stones while taking QUDEXY XR.

• If you take too much QUDEXY XR, call your healthcare provider right away or go to the nearest emergency room.

• QUDEXY XR can be taken before, during, or after a meal.

• If you miss a single dose of QUDEXY XR, take it as soon as you can. If you have missed more than one dose, you should call your healthcare provider for advice.

• Do not stop taking QUDEXY XR without talking to your healthcare provider. Stopping QUDEXY XR suddenly may cause serious problems. 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.

Your healthcare provider may do blood tests while you take QUDEXY XR.
What should I avoid while taking QUDEXY XR?

- You should not drink alcohol while taking QUDEXY XR. QUDEXY XR and alcohol can interact causing side effects such as sleepiness and dizziness.
- Do not drive a car or operate machinery until you know how QUDEXY XR affects you. QUDEXY XR can slow your thinking and motor skills and may affect vision.

What are the possible side effects of QUDEXY XR?

QUDEXY XR may cause serious side effects, including:

See “What is the most important information I should know about QUDEXY XR?”

- High blood ammonia levels. High ammonia in the blood can affect your mental activities, slow your alertness, make you feel tired, or cause vomiting. This has happened when QUDEXY XR is taken with a medicine called valproic acid (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 can cause a drop in body temperature to less than 95°F, or can cause tiredness, confusion, or coma.
- Effects on thinking and alertness. QUDEXY XR may affect how you think, and 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.

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

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
° thickness
° dizziness
° sleeplessness/drowsiness
° a change in the way foods taste
° upper respiratory tract infection
° increased feeling or sensitivity, especially in the skin
° slow reactions
° difficulty with memory
° fever
° abnormal vision
° diarrhea
° pain in the abdomen

These are not all the possible side effects of QUDEXY XR. For more information, ask your healthcare provider or pharmacist.

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

You may also report side effects to Upsher-Smith Laboratories, LLC at 1-855-899-9180.

How should I store QUDEXY XR?

- Store QUDEXY XR capsules at room temperature between 68° to 77°F (20° to 25°C).
- Keep QUDEXY XR in a tightly closed container.
- Keep QUDEXY XR dry and away from moisture.
- Keep QUDEXY XR and all medicines out of the reach of children.

General information about the safe and effective use of QUDEXY XR.

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

What are the ingredients in QUDEXY XR?

Active ingredient: topiramate

Inactive ingredients: microcrystalline cellulose, hypromellose 2910, ethylcellulose, diethyl phthalate, titanium dioxide, black iron oxide, red iron oxide and/or yellow iron oxide, black pharmaceutical ink, and white pharmaceutical ink (200 mg only).

Distributed by: UPSHER-SMITH LABORATORIES, LLC, Maple Grove, MN 55369

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This product may be covered by one or more U.S. patent(s). See www.upshersmithtts.com.

For more information, go to www.upsher-smith.com or call UPSHER-SMITH LABORATORIES, LLC at 1-888-650-3789.

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