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Drug NDC: 62541-0202-30
Drug Name: QSYMIA

What is this medicine?

Phentermine; topiramate (FEN ter meen; toe PYRE a mate) is a combination of two medicines used with a reduced calorie diet and exercise to help you lose weight. This medicine is only available through certified pharmacies enrolled in a special program. Your healthcare professional will tell you where you can get your medicine. If you have additional questions, you can visit the manufacturer's website at www.QsymiaREMS.com or contact them by phone at 1-888-998-4887.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?

Take this medicine by mouth with a glass of water. Follow the directions on the prescription label. Do not crush or chew. This medicine is usually taken with or without food once per day in the morning. Avoid taking this medicine in the evening. It may interfere with sleep. Take your doses at regular intervals. Do not take your medicine more often than directed. A special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time. Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once. NOTE: This medicine is only for you. Do not share this medicine with others.

Where should I keep my medicine?

Keep out of the reach of children. This medicine can be abused. Keep your medicine in a safe place to protect it from theft. Do not share this medicine with anyone. Selling or giving away this medicine is dangerous and against the law. This medicine may cause accidental overdose and death if taken by other adults, children, or pets. Mix any unused medicine with a substance like cat litter or coffee grounds. Then throw the medicine away in a sealed container like a sealed bag or a coffee can with a lid. Do not use the medicine after the expiration date. Store at room temperature between 15 and 25 degrees C (59 and 77 degrees F).

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.

What should I tell my health care provider before I take this medicine?

You need to know if you have any of these conditions: agitation; diarrhea; depression or other mental illness; diabetes; glaucoma; heart disease; high or low blood pressure; history of anorexia or other eating disorder; history of substance abuse; kidney stones or kidney disease; liver disease; lung disease like asthma, obstructive pulmonary disease, emphysema; metabolic acidosis; on a ketogenic diet; scheduled for surgery or a procedure; suicidal thoughts, plans, or attempt; a previous suicide attempt by you or a family member; taken an MAOI like Carbox, Eldepryl, Marplan, Nardil, or Parmate in last 14 days; thyroid disease; an unusual or allergic reaction to phentermine, topiramate, other medicines, foods, dyes, or preservatives; pregnant or trying to get pregnant; breast-feeding.

What if I miss a dose?

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What should I watch for while using this medicine?

Visit your doctor or health care professional for regular checks on your progress. This medicine is intended to be used in addition to a healthy diet and appropriate exercise. The best results are achieved this way. Do not increase or in any way change your dose without consulting your doctor or health care professional. Do not take this medicine within 6 hours of bedtime. It can keep you from getting to sleep. Avoid drinks that contain caffeine and try to stick to a regular bedtime every night. Do not stop taking this medicine suddenly. This increases the risk of seizures. This medicine can decrease sweating and increase your body temperature. Watch for signs of decreased sweating or fever. Avoid extreme heat, hot baths, and saunas. Be careful about exercising, especially in hot weather. Contact your health care provider right away if you notice a fever or decrease in sweating. You should drink plenty of fluids while taking this medicine. If you have had kidney stones in the past, this will help to reduce your chances of forming kidney stones. If you have stomach pain, with nausea or vomiting and yellowing of your eyes or skin, call your doctor immediately. You may get drowsy or dizzy. Do not drive, use machinery, or do anything that needs mental alertness until you know how this medicine affects you. Do not stand or sit up quickly, especially if you are an older patient. This reduces the risk of dizzy or fainting spells. Alcohol may increase dizziness and drowsiness. Avoid alcoholic drinks. This medicine may affect blood sugar levels. If you have diabetes, check with your doctor or health care professional before you change your diet or the dose of your diabetic medicine. Patients and their families should watch out for worsening depression or thoughts of suicide. Also watch out for sudden changes in feelings such as feeling anxious, agitated, panicky, irritable, hostile, aggressive, impulsive, severely restless, overly excited and hyperactive, or not being able to sleep. If this happens, especially at the beginning of treatment or after a change in dose, call your health care professional. If you notice blurred vision, eye pain, or other eye problems, seek medical attention at once for an eye exam. This medicine may increase the chance of developing metabolic acidosis. If left untreated, this can cause kidney stones, bone disease, or slowed growth in children. Symptoms include breathing fast, fatigue, loss of appetite, irregular heartbeat, or loss of consciousness. Call your doctor immediately if you experience any of these side effects. Also, tell your doctor about any surgery you plan on having while taking this medicine since this may increase your risk for metabolic acidosis. Women who become pregnant while using this medicine should contact their physician immediately. You should also contact The Qsymia Pregnancy Surveillance Program which is a program that monitors pregnancies that occur during treatment. Contact the program by calling 1-888-998-4887.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible: allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue; blood in the urine; changes in vision; chest pain or chest tightness; confusion; depressed mood; difficulty breathing; dizziness; fast or irregular heartbeat; feeling anxious; irritable; loss of appetite; low blood pressure; pain in the lower back or side; pain, tingling, numbness in the hands or feet; pain when urinating; palpitations; redness, blistering, peeling or loosening of the skin, including inside the mouth; shortness of breath; suicidal thoughts or other mood changes; trouble passing urine or change in the amount of urine; trouble walking, dizziness, loss of balance or coordination; unusually weak or tired; vomiting. Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome): change in sex drive or performance; changes in vision; constipation; diarrhea; dry mouth; headache; nausea; tremors; trouble sleeping; upset stomach.

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What may interact with this medicine?

Do not take this medicine with any of the following medications:\n\n -MAOIs like Carbox, Eldepryl, Marplan, Nardil, and Parnate\nThis medicine may also interact with the following medications:\n\n -acetazolamide\n -amitriptyline\n -antihistamines for allergy, cough and cold\n -atropine\n -birth control pills\n -carbamazepine\n -certain medicines for bladder problems like oxybutynin, tolterodine\n -certain medicines for depression, anxiety, or psychotic disturbances\n -certain medicines for Parkinson's disease like benztropine, trihexyphenidyl\n -certain medicines for stomach problems like dicyclomine, hyoscyamine\n -certain medicines for travel sickness like scopolamine\n -dichlorphenamide\n -digoxin\n -diltiazem\n -diuretics\n -hydrochlorothiazide\n -ipratropium\n -lithium\n -medicines for diabetes\n -medicines for pain, sleep, or muscle relaxation\n -methazolamide\n -phenytoin\n -pioglitazone\n -stimulant medicines for attention disorders, weight loss, or to stay awake\n -valproic acid\n -zonisamide

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.