MEDICATION GUIDE
QSYMIA® (Kyoo sim ee uh)
(phentermine and topiramate extended-release capsules)
for oral use, CIV

What is the most important information I should know about QSYMIA?
QSYMIA can cause serious side effects, including:

- **Birth defects.** If you take QSYMIA during pregnancy, your baby has a higher risk for birth defects including cleft lip and cleft palate. Your baby may also be smaller than expected at birth. The long-term effects of this are not known. These defects can begin early in pregnancy, even before you know you are pregnant.
  Patients who are pregnant must not take QSYMIA.
  Patients who can become pregnant should:
  1. Have a pregnancy test before taking QSYMIA and every month while taking QSYMIA.
  2. Use effective birth control (contraception) consistently while taking QSYMIA. Talk to your health care provider about how to prevent pregnancy.

  If you become pregnant while taking QSYMIA, stop taking QSYMIA immediately and tell your health care provider right away. Health care providers and patients who become pregnant should report all cases of pregnancy to:
  - FDA MedWatch at 1-800-FDA-1088

  Because of the risk for birth defects (cleft lip and cleft palate), QSYMIA is available through a restricted program called the QSYMIA Risk Evaluation and Mitigation Strategy (REMS). QSYMIA is only available through certified pharmacies that participate in the QSYMIA REMS program. Your health care provider can give you information about how to find a certified pharmacy. For more information, go to www.QSYMIAREMS.com or call 1-888-998-4887.

- **Suicidal thoughts or actions.** Topiramate, an ingredient in QSYMIA, may cause you to have suicidal thoughts or actions.

  Call your health care provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:
  - thoughts about suicide or dying
  - attempts to commit suicide
  - new or worse depression
  - new or worse anxiety
  - feeling agitated or restless
  - panic attacks
  - trouble sleeping (insomnia)
  - new or worse irritability
  - acting aggressive, being angry, or violent
  - acting on dangerous impulses
  - an extreme increase in activity and talking (mania)
  - other unusual changes in behavior or mood

  Do not stop QYSMIA without first talking to a health care provider.
  - Stopping QYSMIA suddenly can cause serious problems.
  - Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your health care provider may check for other causes.

  How can I watch for early symptoms of suicidal thoughts and actions?
  - Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
  - Keep all follow-up visits with your health care provider as scheduled.
  - Call your health care provider between visits as needed, especially if you are worried about symptoms.

- **Serious eye problems** which 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 can lead to permanent vision loss if not treated. Tell your health care provider right away if you have any new eye symptoms.

QSYMIA can have other serious side effects. See "**What are the possible side effects of QSYMIA?**"

What is QSYMIA?

- QSYMIA is a prescription medicine that contains phentermine and topiramate extended-release. QSYMIA may help adults and children 12 years and older with obesity, or some adults with overweight who also have weight-related medical problems, to help them lose excess body weight and keep the weight off.
- QSYMIA should be used with a reduced calorie diet and increased physical activity.
- It is not known if QSYMIA changes your risk of heart problems or stroke or of death due to heart problems or stroke.
- It is not known if QSYMIA is safe and effective when taken with other prescription and over-the-counter medicines, or herbal weight loss products.
- It is not known if QSYMIA is safe and effective in children under 12 years old.
- QSYMIA is a federally controlled substance (CIV) because it contains phentermine and can be abused or lead to drug dependence. Keep QSYMIA in a safe place, to protect it from theft. Never give your QSYMIA to anyone else, because it may cause death or harm them. Selling or giving away QSYMIA is against the law.

Who should not take QSYMIA? Do not take QSYMIA if you:

- are pregnant, planning to become pregnant, or become pregnant during QSYMIA treatment.
- have glaucoma.
- have thyroid problems (hyperthyroidism).
- are taking certain medicines called monoamine oxidase inhibitors (MAOIs) or have taken MAOIs in the past 14 days.
- are allergic to topiramate, sympathomimetic amines such as phentermine, or any of the ingredients in QSYMIA. See the end of this Medication Guide for a complete list of ingredients in QSYMIA.

Before taking QSYMIA, tell your health care provider about all of your medical conditions, including if you:

- have or have had depression, mood problems, or suicidal thoughts or behavior.
- have eye problems, especially glaucoma. See "**Who should not take QSYMIA?**"
- have a history of too much acid in the blood (metabolic acidosis) or a condition that puts you at higher risk for metabolic acidosis such as
  - chronic diarrhea, surgery, a diet high in fat and low in carbohydrates (ketogenic diet), weak, brittle, or soft bones (osteoporosis, osteomalacia (rickets), osteopenia), or decreased bone density.
- have kidney problems, kidney stones, or are getting kidney dialysis.
- have liver problems.
- have seizures or convulsions (epilepsy).
- are allergic to FD&C Yellow No. 5 (tartrazine)
- are breastfeeding or plan to breastfeed. QSYMIA can pass into your breast milk and may harm your baby. You and your health care provider should decide if you will take QSYMIA or breastfeed. You should not do both.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. QSYMIA taken with other medicines may affect how each medicine works and may cause side effects.

Especially tell your health care provider if you take:

- **Birth control pills**. Tell your health care provider if your menstrual bleeding changes while you are taking birth control pills that contain both estrogen and progestin (combination oral contraceptives) and QSYMIA.
- **Water pills** (diuretics) such as hydrochlorothiazide (HCTZ).
- **Any medicines that impair or decrease your thinking, concentration, or muscle coordination.**
- **Carbonic anhydrase inhibitors** such as ZONEGRAN (zonisamide), DIAMOX (acetazolamide) or NEPTAZANE (methazolamide).
- **Seizure medicines** such as Valproic acid (DEPAKENE or DEPAKOTE).

Ask your health care provider or pharmacist for a list of these medicines, if you are not sure.

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

How should I take QSYMIA?

- Your health care provider should start you on a diet and exercise program when you start taking QSYMIA. Stay on this program while you are taking QSYMIA.
- Take QSYMIA exactly as your health care provider tells you to take it.
- **Do not** change your dose without talking to your health care provider.
- Take QSYMIA daily in the morning.
- QSYMIA can be taken with or without food.
- If you miss a dose of QSYMIA, wait until the next morning to take your usual dose of QSYMIA. **Do not** double your dose.
- **To start treatment with QSYMIA**
  - Take 1 **QSYMIA 3.75 mg (phentermine)/23 mg (topiramate) capsule** (Figure A) 1 time each morning for the first 14 days.

- After taking QSYMIA 3.75 mg/23 mg capsule for 14 days, then take 1 **QSYMIA 7.5 mg/46 mg capsule** (Figure B) 1 time each morning.

- **After taking QSYMIA for 12 weeks**
  - Your health care provider may tell you to increase your dose of QSYMIA if you do not lose a certain amount of weight or do not have a certain decrease in BMI for children 12 years and older, within the **first** 12 weeks of treatment at the recommended dose.
- **If your health care provider increases the dose of QSYMIA**
  - Take 1 **QSYMIA 11.25 mg/69 mg capsule** (Figure C) 1 time each morning for 14 days.
  - After taking 14 days of QSYMIA 11.25 mg/69 mg capsule, then take 1 **QSYMIA 15 mg/92 mg capsule** (Figure D) 1 time each morning.
- **Stopping QSYMIA treatment**
  Your health care provider should tell you to stop taking QSYMIA if you have not lost a certain amount of weight or do not have a certain decrease in BMI for children 12 years and older, after an **additional** 12 weeks of treatment on the higher dose.
  Do not stop taking QSYMIA without talking to your health care provider. **Stopping QSYMIA suddenly can cause serious problems, such as seizures**. Your health care provider will tell you how to stop taking QSYMIA slowly.

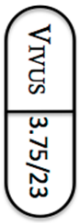

Figure A

QSYMIA (3.75 mg/23 mg)
Cap and body are purple with white printing

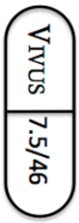

Figure B

QSYMIA (7.5 mg/46 mg)
Cap is purple with white printing and the body is yellow with black printing

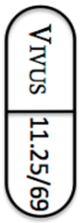

Figure C

QSYMIA (11.25 mg/69 mg)
Cap and body are yellow with black printing

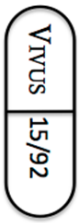

Figure D

QSYMIA (15 mg/92 mg)
Cap is yellow with black printing and the body is white with black printing

If you take too much QSYMIA, call your health care provider or Poison Help line at 1-800-222-1222 or go to the nearest emergency room right away.

What should I avoid while taking QSYMIA?

- **Do not get pregnant while taking QSYMIA.** See "What is the most important information I should know about QSYMIA."
- **Do not drink too much alcohol while taking QSYMIA**. QSYMIA and alcohol can affect each other causing side effects such as sleepiness or dizziness.
- **Do not drive a car, operate heavy machinery, or do other dangerous activities until you know how QSYMIA affects you.** QSYMIA can slow your thinking and motor skills and may affect vision.

What are the possible side effects of QSYMIA?

QSYMIA can cause serious side effects, including:

- See "What is the most important information I should know about QSYMIA?"
- **Mood changes and trouble sleeping.** QSYMIA may cause depression or mood problems, and trouble sleeping. Tell your health care provider if symptoms occur.
- **Concentration, memory, and speech difficulties.** QSYMIA may affect how you think and cause confusion, problems with concentration, attention, memory, or speech. Tell your health care provider if symptoms occur.
- **Slowing of growth.** QSYMIA may slow the increase in height in children 12 years and older, when used for a long time.
- **Increases of acid in bloodstream (metabolic acidosis).** If left untreated, metabolic acidosis can cause brittle or soft bones (osteoporosis, osteomalacia (rickets), osteopenia), kidney stones, can slow the rate of growth in children, and may possibly 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)
- feel changes in heartbeat
- have trouble thinking clearly
  Your health care provider should do a blood test to measure the level of acid in your blood before and during your treatment with QSYMIA.
- **Decrease in kidney function.** QSYMIA may cause a decrease in kidney function. Your health care provider should do a blood test to measure your kidney function before and during treatment with QSYMIA.

- **Possible seizures if you stop taking QSYMIA too fast.** Seizures may happen in people who may or may not have had seizures in the past if you stop QSYMIA too fast. Your health care provider will tell you how to stop taking QSYMIA slowly.
- **Kidney stones.** Drink plenty of fluids when taking QSYMIA to help decrease your chances of getting kidney stones. If you get severe side or back pain, or blood in your urine, call your health care provider.
- **Decreased sweating and increased body temperature (fever).** People should be watched for signs of decreased sweating and fever, especially in hot temperatures. Some people may need to be hospitalized for this condition.
- **Low potassium.** QSYMIA can increase your risk of low potassium levels. Your health care provider should do a blood test to measure the level of potassium in your blood before and during treatment with QSYMIA.
- **Severe multiorgan reactions.** Treatment with QSYMIA may cause a serious allergic reaction that may affect your skin or other parts of your body such as your liver, kidneys, heart, or blood cells. This allergic reaction can be life threatening and can cause death, particularly if it is not treated as early as possible. Contact your healthcare provider or get medical help right away if you have:
    - o blistering and peeling of your skin or skin rash
    - o fever or swollen glands that do not go away
    - o hives
    - o swelling of your face, eyes, lips, tongue, or throat
    - o sores in your mouth
    - o trouble swallowing or breathing
    - o dark urine
    - o yellowing of the skin or whites of the eyes
- **Serious skin reactions**. QSYMIA may cause a severe rash with blisters and peeling skin, especially around the mouth, nose, eyes, and genitals (Stevens-Johnson syndrome). QSYMIA may also cause a rash with blisters and peeling skin over much of the body that may cause death (toxic epidermal necrolysis). Call your health care provider right away if you develop a skin rash or blisters.
- **Allergic reactions.**
    - o Serious allergic reactions can happen after you take QSYMIA. Get emergency help right away if you have swelling of the face, lips, eyes, tongue, or throat, or trouble swallowing or breathing.
    - o QSYMIA capsules contain the inactive ingredient FD&C Yellow No. 5 (tartrazine) which can cause allergic-type reactions (including bronchial asthma) in certain people, especially people who also have an allergy to aspirin.

Common side effects of QSYMIA in adults include:

- o numbness or tingling in the hands, arms, feet, or face (paraesthesia)
- o dizziness
- o change in the way foods taste or loss of taste (dysgeusia)
- o trouble sleeping (insomnia)
- o constipation
- o dry mouth

Common side effects of QSYMIA in children 12 years and older include:

- o depression
- o dizziness
- o joint pain
- o fever
- o flu
- o ankle sprain

Tell your health care provider if you have any side effect that bothers you or does not go away.
These are not all of the possible side effects of QSYMIA. For more information, ask your health care provider or pharmacist.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
You can also report side effects to VIVUS at 1-888-998-4887.

How should I store QSYMIA?

- Store QSYMIA at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep QSYMIA in a tightly closed container.
- Keep QSYMIA dry and away from moisture.

Keep QSYMIA and all medicines out of the reach of children.

General Information about the safe and effective use of QSYMIA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use QSYMIA for a condition for which it was not prescribed. Do not give QSYMIA to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or health care provider for information about QSYMIA that is written for health professionals.

What are the ingredients in QSYMIA?

Active Ingredient: phentermine hydrochloride and topiramate extended-release.

Inactive Ingredients: FD&C Blue #1, FD&C Red #3, FD&C Yellow #5 and #6, ethylcellulose, gelatin, methylcellulose, microcrystalline cellulose, povidone, starch, sucrose, talc, titanium dioxide, and pharmaceutical black and white inks.

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QSYMIA is a registered trademark of VIVUS LLC.

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