

Important Safety Information

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Welcome to the

## Qsymia® (phentermine and topiramate extended-release) capsules CIV Healthcare Provider Training Program

### Overview

FDA has required a Risk Evaluation and Mitigation Strategy (REMS) for Qsymia so that healthcare providers can be informed about the increased risk of teratogenicity associated with Qsymia therapy.

### Purpose

The purpose of the REMS is to inform prescribers and females of reproductive potential (FRP) about the:

- Increased risk of congenital malformations, specifically orofacial clefts, in infants exposed to Qsymia during the first trimester of pregnancy
- Importance of pregnancy prevention for FRP
- Need to discontinue Qsymia immediately if pregnancy occurs

**This is an audio program. You will hear its entire contents via voice-over narration.**

This program should take approximately 20 minutes of your time to complete.



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**Before you consider prescribing Qsymia, it is important to be aware of the increased risk of teratogenicity associated with Qsymia therapy.**

**The information presented in this Training Program does not include a complete list of all risks and safety information on Qsymia.**

**Before prescribing Qsymia, please read the Qsymia Prescribing Information and Qsymia Medication Guide available within this presentation.**

**Further information is also available on the Web site [www.QsymiaREMS.com](http://www.QsymiaREMS.com)**



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## Complete the Qsymia Healthcare Provider Training Program in 3 easy steps:

### Register

Register for the program  
(which includes providing your  
NPI or DEA # for validation)

### Read

Read through the REMS  
information for Qsymia

### Review

Review your knowledge by answering  
some true or false questions



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## Once you complete the program, you will have the opportunity to print out all the Qsymia materials, including:

- Healthcare Provider Counseling Tool for Females of Reproductive Potential
- Prescriber Dosing and Management Checklist
- *Risk of Birth Defects with Qsymia* patient brochure
- Dear Healthcare Provider Letter
- Qsymia Prescribing Information
- Qsymia Medication Guide
- Certificate of Completion



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## Complete the registration form below

First Name	<input type="text"/>	NPI #	<input type="text"/>		
Last Name	<input type="text"/>	DEA #	<input type="text"/>		
Are you a:	MD <input type="radio"/>	DO <input type="radio"/>	PA <input type="radio"/> NP <input type="radio"/>	I am a Kaiser Permanente Healthcare Provider:	<input type="checkbox"/>
Date of Birth	<input type="text"/>	MM/DD/YYYY	Telephone (Optional)	<input type="text"/>	
E-Mail	<input type="text"/>	Confirm E-Mail	<input type="text"/>		

### Why do we need this information?

As part of the Qsymia REMS, it is important to ensure that physicians who are prescribing Qsymia have received training on the teratogenic risks associated with Qsymia.



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## Please provide your address to complete your registration

Address 1	<input type="text"/>	State	<input type="text"/>
Address 2	<input type="text"/>	ZIP	<input type="text"/>
City	<input type="text"/>		



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## Indication and Patient Selection

Qsymia is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:

- 30 kg/m<sup>2</sup> or greater (obese), or
- 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia

### Limitations of use:

- The effect of Qsymia on cardiovascular morbidity and mortality has not been established
- The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established

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## Increased Risk of Teratogenicity

Qsymia is classified as **Pregnancy Category X**

- Qsymia is contraindicated in pregnant women because the use of Qsymia can cause fetal harm. Available data indicate an increase in oral clefts (cleft lip with or without cleft palate) in infants exposed to topiramate, one of the components of Qsymia, during the first trimester of pregnancy.

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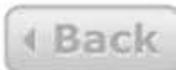
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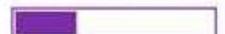
## Increased Risk of Teratogenicity (con't)

**Studies evaluating the risk of major congenital malformations and/or oral clefts with exposure to topiramate, a component of Qsymia, during pregnancy include the following:**

- The North American Anti-Epileptic Drug (NAAED) Pregnancy Registry (2010) analysis
- A retrospective evaluation of a Wolters Kluwer claims database (January 2003-December 2010 from the United States)
- A retrospective observational study using 4 U.S. electronic healthcare databases (FORTRESS)
- A case-control study using data from the Slone Epidemiology Center Birth Defects Study (BDS, 1997-2009) and the Centers for Disease Control's (CDC's) National Birth Defects Prevention Study (NBDPS, 1996-2007)



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## Increased Risk of Teratogenicity (con't)

The NAAED Pregnancy Registry reports an estimated increase in risk for oral clefts of 9.60 (95% CI 3.60-25.70).

An increase in oral clefts was observed with all dose strengths of topiramate.

### SUMMARY OF STUDIES EVALUATING THE ASSOCIATION OF TOPIRAMATE IN UTERO EXPOSURE AND ORAL CLEFTS

EPIDEMIOLOGY STUDY	ORAL CLEFTS		MAJOR CONGENITAL MALFORMATIONS	
	PREVALENCE/ODDS RATIO	95% CI	ESTIMATED INCREASE IN RISK	95% CI
WOLTERS KLUWER*	1.47	0.36-6.06	1.12	0.81-1.55
FORTRESS*	2.22	0.78-6.36	1.21	0.99-1.47
SLONE/CDC	5.36	1.49-20.07	1.01	0.37-3.22

\*Sponsored by the maker of Qsymia® (phentermine and topiramate extended-release) capsules CIV.

CI=confidence interval.

These data show that exposure to topiramate, a component of Qsymia, in pregnancy is associated with a 2- to 5-fold increase in risk of oral clefts.

Other data sources confirm the increased risk of oral clefts with topiramate exposure during pregnancy (ie, animal studies and Adverse Event Reporting System data).



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## Counseling for Females of Reproductive Potential\*

**Qsymia can cause fetal harm.**

**Advise females of reproductive potential that you recommend:**

- Pregnancy testing prior to beginning Qsymia and monthly during therapy
- Use of effective contraception consistently during Qsymia therapy; even females who believe they cannot become pregnant should use effective contraception while taking Qsymia
- If you become pregnant while taking Qsymia, stop Qsymia immediately and notify your healthcare provider

\*Females of reproductive potential are women who have NOT had a hysterectomy, bilateral oophorectomy, or medically documented spontaneous ovarian failure, and have not gone through menopause. Menopause should be clinically confirmed by an individual's healthcare provider.

**Advise nursing mothers not to use Qsymia. Qsymia may be present in human milk because topiramate and amphetamines (phentermine has pharmacologic activity and a chemical structure similar to amphetamines) are excreted in human milk.**



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## Counseling for Females of Reproductive Potential (con't)

**Acceptable Contraception Methods for Females of Reproductive Potential**

<b>Option 1</b> Highly Effective Methods to Use Alone	<b>Option 2</b> Acceptable Methods to Use Together	<b>Option 3</b> Acceptable Methods to Use Together
<b>One method from this list</b> <ul style="list-style-type: none"><li>• Intrauterine device (IUD) or intrauterine system (IUS)<ul style="list-style-type: none"><li>- Copper IUD</li><li>- Levonorgestrel-releasing IUS</li></ul></li><li>• Progestin implant</li><li>• Tubal sterilization</li><li>• Male partner's vasectomy</li></ul>	<b>One method from this list</b> <p><b>Hormonal Contraception</b></p> <ul style="list-style-type: none"><li>• Estrogen and progestin<ul style="list-style-type: none"><li>- Oral (the pill)</li><li>- Transdermal patch</li><li>- Vaginal ring</li></ul></li><li>• Progestin only<ul style="list-style-type: none"><li>- Oral</li><li>- Injection</li></ul></li></ul>	<b>One method from this list</b> <p><b>Barrier Method</b></p> <ul style="list-style-type: none"><li>• Diaphragm (with spermicide)</li><li>• Cervical cap (with spermicide)</li></ul>
	+	
		<b>One method from this list</b> <p><b>Barrier Method</b></p> <ul style="list-style-type: none"><li>• Male condom (with or without spermicide)</li></ul>



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## Dispensed to Patients Through Certified Pharmacies

Qsymia is available only through certified pharmacies that provide a Qsymia Medication Guide and *Risk of Birth Defects with Qsymia* patient brochure with every prescription and refill as required by the REMS.

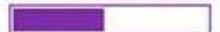
Please note that Qsymia is not available outside this network of certified pharmacies. (A full listing of certified pharmacies can be accessed at the end of this presentation.)

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extended-release) capsules 

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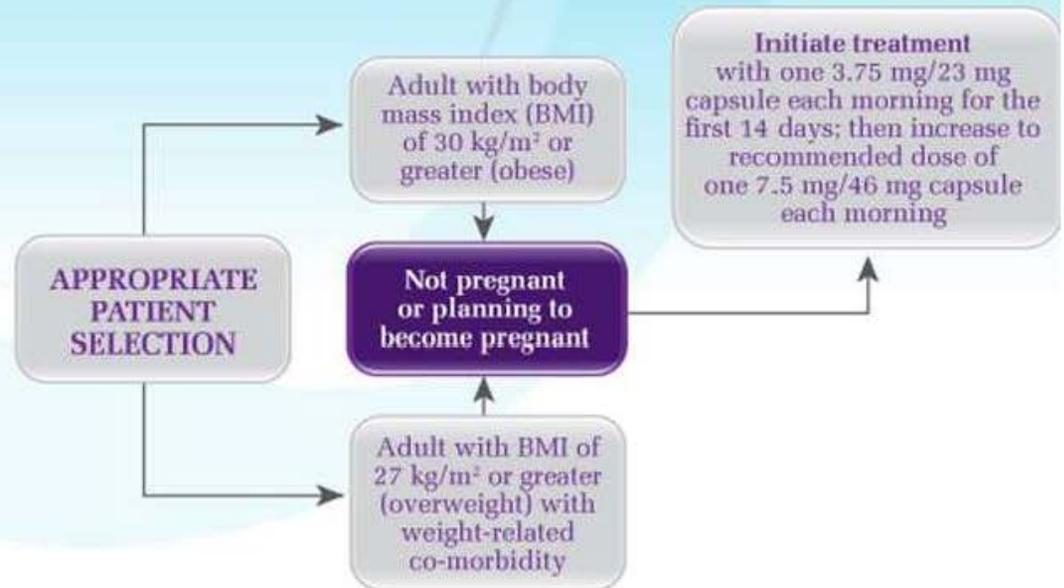
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## Dosage and Administration

### Initiation of Treatment

- Qsymia should be taken in the morning, with or without food
- Avoid dosing with Qsymia in the evening due to the possibility of insomnia
- For patients with moderate hepatic impairment or moderate/severe renal impairment, the Qsymia dose should not exceed the recommended dose of Qsymia 7.5 mg/46 mg (phentermine 7.5 mg/topiramate 46 mg extended-release)
- The suggested follow-up after administration of initial treatment is 2 to 8 weeks
- To initiate treatment: Start with one Qsymia 3.75 mg/23 mg (phentermine 3.75 mg/topiramate 23 mg extended-release) capsule each morning for the first 14 days; then increase to recommended dose of one Qsymia 7.5 mg/46 mg capsule each morning



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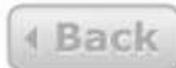
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## Dosage and Administration (con't)

**Evaluate weight loss with the recommended dose of Qsymia, 7.5 mg/46 mg, at week 12 of treatment**

If a patient has not lost at least 3% of baseline body weight on the recommended dose of Qsymia, 7.5 mg/46 mg, discontinue Qsymia or escalate the dose as directed, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss at the Qsymia 7.5 mg/46 mg dose.

To escalate the dose: Increase to one Qsymia 11.25 mg/69 mg (phentermine 11.25 mg/topiramate 69 mg extended-release) capsule each morning for 14 days, followed by dosing one Qsymia 15 mg/92 mg (phentermine 15 mg/topiramate 92 mg extended-release) capsule each morning.



## Dosage and Administration (con't)

### Evaluate weight loss following dose escalation to Qsymia 15 mg/92 mg after 12 weeks of treatment

If a patient has not lost at least 5% of baseline body weight on Qsymia 15 mg/92 mg, discontinue Qsymia, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

To discontinue Qsymia 15 mg/92 mg, have the patient take a dose every other day for at least 1 week prior to stopping treatment altogether, due to the possibility of precipitating a seizure with abrupt cessation of dosing.



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**Please complete your certification by taking the following brief quiz.**



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**True or False:** The major risk for females of reproductive potential (FRP) being treated with Qsymia is that of teratogenicity (birth defects), specifically the risk of cleft lip with or without cleft palate.



True



False

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**True or False:** The major risk for females of reproductive potential (FRP) being treated with Qsymia is that of teratogenicity (birth defects), specifically the risk of cleft lip with or without cleft palate.



True



False

**The correct answer is TRUE.**

Topiramate, a component of Qsymia, has been associated with an increased risk of cleft lip with or without cleft palate in infants exposed to topiramate during the first trimester of pregnancy.



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**True or False:** If a patient hasn't achieved 3% weight loss following 12 weeks of treatment on the recommended dose of Qsymia 7.5 mg/46 mg (phentermine 7.5 mg/topiramate 46 mg extended-release), discontinuation of therapy or dose escalation should be considered.



True



False

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**True or False:** If a patient hasn't achieved 3% weight loss following 12 weeks of treatment on the recommended dose of Qsymia 7.5 mg/46 mg (phentermine 7.5 mg/topiramate 46 mg extended-release), discontinuation of therapy or dose escalation should be considered.



True



False

**The correct answer is TRUE.**

If a patient has not lost at least 3% of baseline body weight on Qsymia 7.5 mg/46 mg, discontinue Qsymia or escalate the dose as directed, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss at the Qsymia 7.5 mg/46 mg dose.

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**True or False:** Women taking Qsymia should use contraception unless they have had infertility or trouble getting pregnant in the past.



True



False

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**True or False:** Women taking Qsymia should use contraception unless they have had infertility or trouble getting pregnant in the past.



True



False

The correct answer is **FALSE**.

ALL women, except those who have gone through menopause or undergone surgical sterilization, should be advised to consistently use effective contraception, even women who have had difficulty getting pregnant in the past.

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**True or False:** If I don't think a patient is at risk for pregnancy, I don't need to discuss contraception.

True

False

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**True or False:** If I don't think a patient is at risk for pregnancy, I don't need to discuss contraception.



True



False

**The correct answer is FALSE.**

It is important to have this conversation with all patients. It is important to know whether a patient is:

- Trying to get pregnant and not using contraception, in which case do not prescribe Qsymia
- Sexually active and what contraception she is using, in which case reinforce the importance of consistent use of effective contraception
- Surgically sterilized or has gone through menopause that has been clinically confirmed, in which case no contraception is required

It is important to have this conversation with all patients, so that if there is a female of reproductive potential in the house, the patient knows to keep Qsymia in a secure location and not share it with anyone else.



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**True or False:** If a woman thinks she is pregnant, she should continue taking Qsymia until the pregnancy is confirmed.



True



False

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**True or False:** If a woman thinks she is pregnant, she should continue taking Qsymia until the pregnancy is confirmed.



True



False

**The correct answer is FALSE.**

If a woman believes she might be pregnant, she should stop taking Qsymia immediately and contact her healthcare provider.

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5 of 5 True taking

The correct answer is...  
If a woman believes she...  
contact her healthcare...

she should continue

a immediately and

**Please review the Qsymia Prescribing Information and Qsymia Medication Guide before prescribing.**

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## Congratulations!

You have completed the Qsymia Healthcare Provider Training Program. Take this opportunity to review printable versions of the Qsymia REMS materials by clicking on the links below or learn more about Qsymia by going to [www.QsymiaREMS.com](http://www.QsymiaREMS.com).

- [Healthcare Provider Counseling Tool for Females of Reproductive Potential](#)
- [Prescriber Dosing and Management Checklist](#)
- [Risk of Birth Defects with Qsymia patient brochure](#)
- [Dear Healthcare Provider Letter](#)
- [Qsymia Prescribing Information](#)
- [Qsymia Medication Guide](#)
- [Certificate of Completion](#)
- [Certified Pharmacy Locator on \[www.QsymiaREMS.com\]\(http://www.QsymiaREMS.com\)](#)



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to review  
about Qsymia by

### Qsymia<sup>®</sup> (phentermine and topiramate extended-release) capsules CIV Healthcare Provider Training Program

Name: **John Q. Sample**

Date: **August 18, 2014**

This certificate confirms that you have completed the Qsymia  
Healthcare Provider Training Program.

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For more information, contact VIVUS Medical Information  
at 1-888-998-4887 or visit  
[www.QsymiaREMS.com](http://www.QsymiaREMS.com)

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### **Important Safety Information**

Qsymia® is contraindicated in pregnancy; in patients with glaucoma; in hyperthyroidism; in patients receiving treatment or within 14 days following treatment with monoamine oxidase inhibitors (MAOIs); or in patients with hypersensitivity or idiosyncrasy to sympathomimetic amines, topiramate, or any of the inactive ingredients in Qsymia.

Qsymia can cause fetal harm. Females of reproductive potential should have a negative pregnancy test before treatment and monthly thereafter and use effective contraception consistently during Qsymia therapy. If a patient becomes pregnant while taking Qsymia, treatment should be discontinued immediately, and the patient should be informed of the potential hazard to the fetus.

Qsymia can cause an increase in resting heart rate. Regular measurement of resting heart rate is recommended for all patients taking Qsymia, especially patients with cardiac or cerebrovascular disease or when initiating or increasing the dose of Qsymia. Qsymia has not been studied in patients with recent or unstable cardiac or cerebrovascular disease and therefore use is not recommended.

Topiramate, a component of Qsymia, increases the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue Qsymia in patients who experience suicidal thoughts or behaviors. Qsymia is not recommended in patients with a history of suicidal attempts or active suicidal ideation.

Acute angle closure glaucoma has been reported in patients treated with topiramate, a component of Qsymia. Symptoms include acute onset of decreased visual acuity and/or eye pain. Symptoms typically occur within 1 month of initiating treatment with topiramate but may occur at any time during therapy. The primary treatment to reverse symptoms is immediate discontinuation of Qsymia.

Qsymia can cause mood disorders, including depression, and anxiety, as well as insomnia. Qsymia can cause cognitive dysfunction (e.g., impairment of concentration/attention, difficulty with memory, and speech or language problems, particularly word-finding difficulties). Since Qsymia has the potential to impair cognitive function, patients should be cautioned about operating hazardous machinery, including automobiles.

Hyperchloremic, non-anion gap, metabolic acidosis has been reported in patients treated with Qsymia. If metabolic acidosis develops and persists, consideration should be given to reducing the dose or discontinuing Qsymia.

Qsymia can cause an increase in serum creatinine. If persistent elevations in creatinine occur while taking Qsymia, reduce the dose or discontinue Qsymia.

**This information comes from a link to [QsymiaREMS.com](https://www.QsymiaREMS.com)**

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use QSYMIA® safely and effectively. See full prescribing information for QSYMIA.

**QSYMIA (phentermine and topiramate extended-release) capsules, for oral use, CIV**  
**Initial U.S. Approval: 2012**

**INDICATIONS AND USAGE**

Qsymia is a combination of phentermine, a sympathomimetic amine anorectic, and topiramate extended-release, an antiepileptic drug, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m<sup>2</sup> or greater (obese) (1) or
- 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia (1)

**Limitations of Use:**

- The effect of Qsymia on cardiovascular morbidity and mortality has not been established (1).
- The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established (1).

**DOSAGE AND ADMINISTRATION**

- Take once daily in morning. Avoid evening dose to prevent insomnia (2.1).
- Recommended dose: Qsymia 3.75 mg/23 mg (phentermine 3.75 mg/topiramate 23 mg extended-release) daily for 14 days; then increase to 7.5 mg/46 mg daily (2.1).
- Discontinue or escalate dose (as described) if 3% weight loss is not achieved after 12 weeks on 7.5 mg/46 mg dose (2.1).
- Discontinue Qsymia if 5% weight loss is not achieved after 12 weeks on maximum daily dose of 15 mg/92 mg (2.1).
- Discontinue 15 mg/92 mg dose gradually (as described) to prevent possible seizure (2.1).
- Do not exceed 7.5 mg/46 mg dose for patients with moderate or severe renal impairment or patients with moderate hepatic impairment (2.2, 2.3).

**DOSAGE FORMS AND STRENGTHS**

Capsules: (phentermine mg/topiramate mg extended-release)

- 3.75 mg/23 mg (3)

- Known hypersensitivity or idiosyncrasy to sympathomimetic amines (4)

**WARNINGS AND PRECAUTIONS**

- **Fetal Toxicity:** Females of reproductive potential: Obtain negative pregnancy test before treatment and monthly thereafter; use effective contraception. Qsymia is available through a limited program under a Risk Evaluation and Mitigation Strategy (REMS) (5.1).
- **Increase in Heart Rate:** Monitor heart rate in all patients, especially those with cardiac or cerebrovascular disease (5.2).
- **Suicidal Behavior and Ideation:** Monitor for depression or suicidal thoughts. Discontinue Qsymia if symptoms develop (5.3).
- **Acute Myopia and Secondary Angle Closure Glaucoma:** Discontinue Qsymia (5.4).
- **Mood and Sleep Disorders:** Consider dose reduction or withdrawal for clinically significant or persistent symptoms (5.5).
- **Cognitive Impairment:** May cause disturbances in attention or memory. Caution patients about operating automobiles or hazardous machinery when starting treatment (5.6).
- **Metabolic Acidosis:** Measure electrolytes before/during treatment (5.7).
- **Elevated Creatinine:** Measure creatinine before/during treatment (5.8).
- **Use of Antidiabetic Medications:** Weight loss may cause hypoglycemia. Measure serum glucose before/during treatment (5.9).

**ADVERSE REACTIONS**

Most common adverse reactions (incidence greater than or equal to 5% and at a rate at least 1.5 times placebo) are: paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth (6.1).

**To report SUSPECTED ADVERSE REACTIONS, contact VIVUS Inc., at 1-888-998-4887 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**DRUG INTERACTIONS**

- **Oral contraceptives:** Altered exposure may cause irregular bleeding but not increased risk of pregnancy. Advise patients not to discontinue oral contraceptives if spotting occurs (7.2).
- **CNS depressants including alcohol:** Potentiate CNS depressant effects. Avoid concomitant use of alcohol (7.3).
- **Non-potassium sparing diuretics:** May potentiate hypokalemia. Measure potassium before/during treatment (7.4).

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**MEDICATION GUIDE**  
**QSYMIA® (Kyoo sim ee' uh)**  
**(phentermine and topiramate extended-release)**  
**Capsules CIV**

**Read this Medication Guide** before you start taking Qsymia and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. If you have any questions about Qsymia, talk to your healthcare provider or pharmacist.

**What is the most important information I should know about Qsymia?**

(For other side effects, also see **“What are the possible side effects of Qsymia?”**)

Qsymia can cause serious side effects, including:

- **Birth defects (cleft lip/cleft palate).** If you take Qsymia 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.

**Women who are pregnant must not take Qsymia.**

**Women who can become pregnant should:**

1. Have a negative pregnancy test before taking Qsymia and every month while taking Qsymia.
2. Use effective birth control (contraception) consistently while taking Qsymia. Talk to your healthcare provider about how to prevent pregnancy.

**If you become pregnant while taking Qsymia, stop taking Qsymia immediately, and tell your healthcare provider right away.** Healthcare providers and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- The Qsymia Pregnancy Surveillance Program at 1-888-998-4887

- **Increases in heart rate.** Qsymia can increase your heart rate at rest. Your

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