Qsymia®
(phentermine and topiramate extended-release) capsules [C]

Prescriber Dosing and Management Checklist

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/m² or greater (obese) or
- 27 kg/m² 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

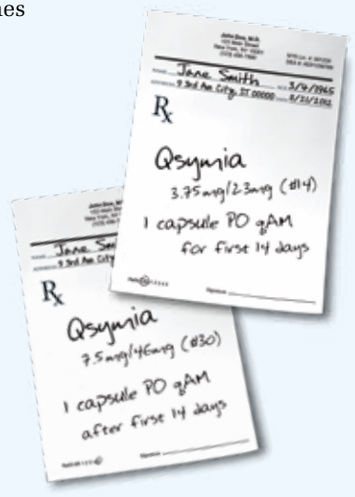
Identify Appropriate Patients

- ☐ BMI* 30 or greater (obese) or BMI 27 or greater (overweight) with at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia
- ☐ Must NOT be pregnant, trying to get pregnant, or unable/unwilling to comply with contraceptive guidance
- ☐ Must not have glaucoma
- ☐ Must not have hyperthyroidism
- ☐ Must not be using monoamine oxidase inhibitors (MAOIs) or have used them within 14 days
- ☐ Must not have known hypersensitivity or idiosyncrasy to the sympathomimetic amines

Start

Write 2 prescriptions:

- Qsymia 3.75 mg/23 mg (starting dose) for the first 14 days
- Qsymia 7.5 mg/46 mg (recommended dose) after the first 14 days
- Once daily, in the morning, with or without food
- Moderate hepatic impairment or moderate/severe renal impairment: dose should not exceed 7.5 mg/46 mg
- Suggested follow-up: 2–8 weeks



Instruct patients to begin Qsymia treatment as follows:

1. Take only one 3.75 mg/23 mg† capsule each morning for the first 14 days of treatment.
2. AFTER the first 14 days of 3.75 mg/23 mg treatment is complete, take one 7.5 mg/46 mg† capsule each morning.
3. Do NOT take 3.75 mg/23 mg and 7.5 mg/46 mg at the same time.

Counsel Patients

Counsel patients at each visit to:

- Consistently use contraception to avoid pregnancy because of the increased risk of teratogenicity, if she is a female of reproductive potential. Refer these patients to the *Risk of Birth Defects with Qsymia®* patient brochure
- Modify their lifestyle, eat properly, and engage in regular physical activity
- Not share Qsymia with anyone else
- Report any symptoms of concern

Monitor Patients

Monitor all patients at each visit for:

- Weight, status of comorbidities, and achievement of goals
- Adjustments/modifications to concomitant medications
- Use of effective contraception, if applicable. Test for pregnancy on a monthly basis if patient is a female of reproductive potential
- Heart rate: discontinue for sustained elevations
- Emergent/worsening depression, suicidal thoughts or behaviors
- Important side effects (e.g., cognitive dysfunction, glaucoma, metabolic acidosis, kidney stones)
  - Consider lowering dose or discontinuing medication for patients who experience important side effects

After 12 weeks at recommended dose of 7.5 mg/46 mg†:

- If weight loss less than 3%, discontinue Qsymia or escalate the dose
- To escalate dose, write 2 prescriptions:
  - Qsymia 11.25 mg/69 mg (titration dose) for 14 days
  - Qsymia 15 mg/92 mg after 14 days
- Qsymia 3.75 mg/23 mg and Qsymia 11.25 mg/69 mg are for titration purposes only
- Instruct patients to escalate the Qsymia dose as follows:
  1. Take only one 11.25 mg/69 mg† capsule each morning for 14 days of dose escalation.
  2. AFTER the 14 days of dose escalation with 11.25 mg/69 mg is complete, take only one 15 mg/92 mg† capsule each morning.
  3. Do NOT take 11.25 mg/69 mg and 15 mg/92 mg at the same time.

After additional 12 weeks following dose escalation to 15 mg/92 mg:

- If weight loss less than 5% after 12 weeks, discontinue treatment
- Discontinue Qsymia 15 mg/92 mg gradually by taking a dose every other day for at least 1 week prior to stopping altogether, due to the possibility of precipitating a seizure with abrupt cessation of the drug

*BMI is measured in kg/m².
†Pills not shown as actual size.

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.

Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus treated with insulin and/or insulin secretagogues (e.g., sulfonylureas). Qsymia has not been studied in combination with insulin. A reduction in the dose of antidiabetic medications which are non-glucose-dependent should be considered to mitigate the risk of hypoglycemia.

The most commonly observed side effects in controlled clinical studies, ≥5% and at least 1.5 times placebo, include paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth.

To report negative side effects, contact VIVUS Inc., at 1-888-998-4887 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

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