Risk Evaluation and Mitigation Strategy (REMS)

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks. The FDA has required a REMS for Qsymia.

The purpose of the Qsymia REMS is to inform certified pharmacies and patients of reproductive potential about the:

- Increased risk of congenital malformation, specifically orofacial clefts, in infants exposed to Qsymia during the first trimester of pregnancy
- Importance of pregnancy prevention for patients of reproductive potential receiving Qsymia
- Need to discontinue Qsymia immediately if pregnancy occurs

Dispensed to Patients Through Certified Pharmacies

Qsymia is available only through certified pharmacies. Click Here to learn more.

For additional information, please contact VIVUS Medical Information at: 1-888-998-4887
Welcome to the Qsymia® (phentermine and topiramate extended-release) capsules CIV Pharmacy Training Program

The Qsymia REMS Pharmacy Training Program is designed to provide pharmacists with an understanding of the risks of Qsymia and the Pharmacy requirements under the REMS.

Enrollment in the Qsymia REMS Pharmacy Program is necessary to dispense Qsymia.

Before you can enroll in the Qsymia REMS Pharmacy Program, you must:

1. Review the Qsymia REMS Pharmacy Training Program
2. Successfully complete the Knowledge Assessment questions
3. Sign the acknowledgement statement on the enrollment form

Start the Qsymia Pharmacy Training Program

The Qsymia REMS Pharmacy Training Program and Knowledge Assessment questions can be downloaded using this link.

For assistance, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698

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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/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

For assistance, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698
Increased Risk of Teratogenicity

- Qsymia is contraindicated in pregnant patients 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.

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:

- 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)

The NAAED Pregnancy Registry suggested 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. **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

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

![Table of studies](image)

*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 (i.e., animal studies and Adverse Event Reporting System data).

For assistance, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698
Counseling Provided by HCPs for Patients of Reproductive Potential*

Qsymia can cause fetal harm.

Advise patients of reproductive potential that labeling recommends:

- Pregnancy testing prior to beginning Qsymia and monthly during therapy. Specific documentation of the result is not required at the pharmacy level
- Use of effective contraception consistently during Qsymia therapy because Qsymia can cause certain kinds of birth defects (oral clefts). Even patients who believe they cannot become pregnant should use effective contraception while taking Qsymia due to the potential for increased fertility associated with weight loss
- If a patient becomes pregnant while taking Qsymia, Qsymia should be discontinued immediately and the patient advised to notify their healthcare provider

Acceptable Contraception Methods for Patients of Reproductive Potential

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Highly Effective Methods to Use Alone</strong></td>
<td><strong>Acceptable Methods to Use Together</strong></td>
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<td><strong>One method from this list</strong></td>
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<td>- Progestin implant</td>
<td>- Transdermal patch</td>
<td>- Male condom (with or without spermicide)</td>
</tr>
<tr>
<td>- Tubal sterilization</td>
<td>- Vaginal ring</td>
<td>OR</td>
</tr>
<tr>
<td>- Male partner’s vasectomy</td>
<td>- Progestin only</td>
<td>- One method from this list</td>
</tr>
<tr>
<td>OR</td>
<td>- Oral</td>
<td>- Barrier Method</td>
</tr>
<tr>
<td></td>
<td>- Injection</td>
<td>- Cervical cap (with spermicide)</td>
</tr>
</tbody>
</table>

*Patients of reproductive potential are patients 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.

For assistance, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698

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Qsymia is only dispensed through Certified Pharmacies

Under the REMS, Qsymia is only available through certified pharmacies. To become a certified pharmacy, an authorized or responsible pharmacy representative must agree to:

1. Refrain from reselling or transferring Qsymia to another pharmacy or distributor.
2. Train pharmacists and staff involved with the dispensing of Qsymia about the risks associated with Qsymia and the REMS requirement to provide a Medication Guide and Risk of Birth Defects with Qsymia patient brochure each time Qsymia is dispensed.
3. To be subject to and comply with surveys or audits (as applicable) to evaluate understanding of the risks associated with the use of Qsymia, and compliance with the requirements of the REMS.

The list of certified pharmacies will be updated within 1-2 business days after a new pharmacy is certified and eligible to dispense. Prescribers and patients will be able to use a "Certified Pharmacy Locator" tool to identify certified pharmacies in their area and can be found at www.QsymiaREMS.com

Please note that Qsymia is not available outside this network of certified pharmacies.

For assistance, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698
Dispensing Conditions

Qsymia must be dispensed with a Medication Guide and the Risk of Birth Defects with Qsymia patient brochure each time Qsymia is dispensed.

Prescriber Dosing and Management Algorithm

- Prescriber needs to initiate treatment by providing two prescriptions
  - one for 3.75 mg/23 mg 1 po qAM #14 (no refills) and
  - a second for 7.5 mg/46 mg 1 po qAM #30 (with refills potentially)

- Prescriber needs to escalate dose by providing two prescriptions
  - one for 11.25 mg/69 mg 1 po qAM #14 (no refills) and
  - a second for 15 mg/92 mg 1 po qAM #30 (with refills potentially)

Only one Qsymia capsule to be taken daily, using sequence for dose escalations noted above.

Please see Qsymia Prescribing Information.

For assistance, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698
Patient Counseling

1. The Medication Guide and patient brochure contain important information that patients should read and become familiar with.
2. Qsymia should be taken in the morning, with or without food.
3. Avoid taking Qsymia in the evening due to the possibility of insomnia.
4. Advise patients to start treatment with Qsymia as follows:
   - Take one Qsymia 3.75 mg/23 mg capsule once each morning for the first 14 days
   - After the first 14 days is complete, take one Qsymia 7.5 mg/46 mg capsule once each morning
   - Do not take Qsymia 3.75 mg/23 mg and Qsymia 7.5 mg/46 mg capsules together
5. If an increase in Qsymia dose is prescribed after medical evaluation, advise patients to increase the dose of Qsymia as follows:
   - Take one Qsymia 11.25 mg/69 mg capsule once each morning for 14 days
   - After the 14 days is complete, take one Qsymia 15 mg/92 mg capsule once each morning
   - Do not take Qsymia 11.25 mg/69 mg and Qsymia 15 mg/92 mg capsules together
6. Advise patients NOT to stop Qsymia without talking with their HCP as serious side effects such as seizures may occur.

For assistance, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698
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. Patients of reproductive potential should have a 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 LLC at 1-888-998-4887 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For assistance, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698

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Risk Evaluation and Mitigation Strategy (REMS)

Additional Information and Tools

Additional information and tools can be found at www.QsymiaREMS.com

- Risk of Birth Defects with Qsymia patient brochure
- Qsymia Prescribing Information
- Qsymia Medication Guide

For more information on Qsymia or the Qsymia REMS Pharmacy Program, or for information on Pharmacy Certification, contact Qsymia REMS Pharmacy Support Center at 1-855-302-6698 or visit www.QsymiaREMS.com.

For assistance, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698
IMPORTANT PROGRAM UPDATE

Beginning March 25, 2022, the Qsymia REMS program and www.qsymiarems.com will be updated to accommodate the removal of the current "switch" pharmacy management system. For questions or further information please email REMS@vivus.com.

Information for Pharmacists

Qsymia is only available through certified pharmacies. Certified pharmacies must follow the requirements of the Qsymia REMS program.

Steps for pharmacy certification:

1. Successful completion of Pharmacy Training Program and knowledge assessment
2. Completion of appropriate Pharmacy Enrollment form-acknowledging and agreeing to pharmacy requirements
   - Corporate Entity of Retail Chain Pharmacy—Authorized Pharmacy Representative (responsible for internally coordinating and overseeing the Qsymia REMS program for their organization)
   - Independent Retail Pharmacies—Authorized Pharmacy Representative (responsible for internally coordinating and overseeing the Qsymia REMS program requirements)
   - Mail Order Pharmacies—Authorized Pharmacy Representative (responsible for internally coordinating and overseeing the Qsymia REMS program requirements)

Search for Certified Pharmacies

Search now.

For assistance, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698
Search for a Certified Pharmacy near you

Enter your zip code to locate a certified pharmacy within 20 miles of your zip code.

Qsymia is also available by mail order through the Qsymia Home Delivery Network:

medvantx  
P: 1-844-777-9642  
F: 1-844-678-8444

Walgreens  
P: 1-877-487-8800  
F: 1-800-332-9581

Walmart Pharmacy  
P: 1-800-273-3455  
F: 1-800-406-8976

For additional information, please contact VIVUS Medical Information at: 1-888-998-4887

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Search for a Qsymia® Certified Pharmacy Retail Location

Sort by:  ✔ Distance  ○ Pharmacy Name  

10 Pharmacies near 59718

Map  Satellite

1  COSTCO PHARMACY  < 1 mile
2505 CATRON ST
BOZEMAN, MT 59718
Phone: 406-585-7575

2  COSTCO PHARMACY  1.4 miles
1400 N 19TH AVE
BOZEMAN, MT 59718
Phone: 406-586-3550

3  COSTCO PHARMACY  1.8 miles
1500 N 7TH AVE
BOZEMAN, MT 59715
Phone: 406-585-8753

4  COSTCO PHARMACY  2.0 mile
1126 N 7TH AVE
BOZEMAN, MT 59715
Phone: 406-587-8570

5  COSTCO PHARMACY  2.1 miles
910 N. 7th Ave.
Bozeman, MT 59715
Phone: 406-587-0608

6  COSTCO PHARMACY  2.4 miles
1525 W MAIN ST
BOZEMAN, MT 59715
Phone: 406-587-9252

7  COSTCO PHARMACY  2.6 miles
200 S 23RD AVE
BOZEMAN, MT 59718
Phone: 406-587-8800

8  COSTCO PHARMACY  4.0 miles
925 HIGHLAND BLVD STE 2000
BOZEMAN, MT 59715
Phone: 406-585-5030

9  COSTCO PHARMACY  6.9 miles
6999 JACKRABBIT LN
BELGRADE, MT 59714
Phone: 406-388-1696

10 COSTCO PHARMACY  < 24.4 miles
2120 PARK ST S
LIVINGSTON, MT 59047
Phone: 406-222-1188

For additional information, please contact VIVUS Medical Information at: 1-888-998-4887
Risk of Birth Defects with Qsymia®
(phentermine and topiramate extended-release) capsules CIV

Please read the following important safety information about the use of Qsymia in patients who can become pregnant.

You are considered a patient who can become pregnant if this applies to you:

- You have never had a hysterectomy (uterus removed), surgical sterilization (tubes tied), or both ovaries removed and

- You have not gone through menopause. Menopause should be confirmed by your healthcare provider

1) Qsymia can increase the risk of a birth defect called cleft lip or cleft palate (as shown in the picture)

   - These defects happen early in pregnancy, sometimes even before you know you are pregnant

2) You should have a pregnancy test taken BEFORE starting treatment with Qsymia and EVERY MONTH after that while on treatment

   - Talk with your healthcare provider about when and where to have your pregnancy testing performed

   - If you have a positive pregnancy test, or you miss a period, or you think you might be pregnant, you must not start Qsymia, or if you are already taking Qsymia, you should stop it immediately and tell your healthcare provider right away

3) While you are on Qsymia therapy, you should use effective birth control methods every time you have sex with a male

   - Certain birth control methods are effective when used alone. Other birth control methods are not as effective by themselves, so you should use a second method of birth control

Talk to your healthcare provider to help decide what birth control options are best for you.

Please see the chart on the back to review birth control options.
Your Birth Control Options

**OPTION 1**
Highly Effective Methods to Use Alone

- Intrauterine device (IUD) or intrauterine system (IUS)
- Copper IUD
- Levonorgestrel-releasing IUS
- Progestin implant
- Tubal sterilization
- Male partner’s vasectomy

OR

**OPTION 2**
Acceptable Methods to Use Together

- **Hormonal Contraception**
  - Estrogen and progestin
    - Oral (the pill)
    - Transdermal patch
    - Vaginal ring
    - Progestin only
      - Oral
      - Injection

**OPTION 3**
Acceptable Methods to Use Together

- **Barrier Method**
  - Diaphragm (with spermicide)
  - Cervical cap (with spermicide)

Keep in mind, even the most effective birth control methods can fail. But your chances of getting pregnant are lowest if the methods you choose are always used correctly and every time you have sex.

Please read the accompanying Qsymia® Medication Guide as it contains additional important safety information about your treatment. 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, contact VIVUS Medical Information at 1-888-998-4887, or visit the Web site www.QsymiaREMS.com.