

[Important Safety Information](#) | [Full Prescribing Information](#) | [Medication Guide](#)

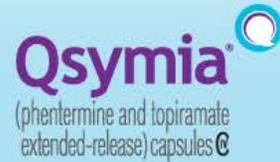
[Healthcare Provider  
Training Program](#)

[Pharmacy  
Training Program](#)

[Information for  
Pharmacists](#)

[Qsymia Certified  
Pharmacy Network](#)

[Risk of Birth Defects  
Patient Brochure](#)



## 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 prescribers and females 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 females of reproductive potential receiving Qsymia
- Need to discontinue Qsymia immediately if pregnancy occurs

### Healthcare Provider Training Program

The Qsymia REMS includes a healthcare provider training program.

Complete the Qsymia Healthcare  
Provider Training Program

**START**

### Counseling Females on Risk of Birth Defects with Qsymia

- Counsel females of reproductive potential at initial and all follow-up visits on the increased risk of orofacial clefts in infants exposed to Qsymia during the first trimester of pregnancy
- Counsel females of reproductive potential to have a pregnancy test before starting Qsymia and monthly thereafter during therapy
- Discuss the need for consistent use of effective contraception during therapy
- Make use of the REMS tools supporting patient education that are available on this Web site

### Dispensed to Patients Through Certified Pharmacies

Qsymia is available only through certified pharmacies. [Click Here](#) to learn more.

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RE-03-010-02 08/2014

#### Materials for Healthcare Providers

[Healthcare Provider Counseling Tool  
for Females of Reproductive Potential](#)  
[Prescriber Dosing and Management Checklist](#)  
[Healthcare Provider Training Program](#)  
[Dear Healthcare Provider Letter](#)  
[Full Prescribing Information](#)

#### Materials for Patients

[Risk of Birth Defects with Qsymia patient brochure](#)  
[Medication Guide](#)

These materials can be downloaded and printed.

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