Dear Medical Society Letter

Qsymia®
(phentermine and topiramate extended-release) capsules CIV

IMPORTANT DRUG WARNING –
REMS required for Qsymia® (phentermine and topiramate extended-release) capsules CIV

Subject: Risk of Teratogenicity with Qsymia
FDA-Required Risk Evaluation and Mitigation Strategy (REMS)

Date

Dear Medical Society:

VIVUS would like to inform you of the increased risk of teratogenicity with Qsymia in order to ensure its safe and appropriate use. This letter does not describe all the risks associated with Qsymia.

Qsymia is a schedule IV controlled substance (C-IV).

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^2 or greater (obese), or
- 27 kg/m^2 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

The Food and Drug Administration (FDA) determined a Risk Evaluation and Mitigation Strategy is necessary to ensure the benefits of Qsymia outweigh the increased risk of teratogenicity.

Risk of Teratogenicity associated with Qsymia therapy

- Qsymia can cause fetal harm. A fetus exposed to topiramate, a component of Qsymia, in the first trimester of pregnancy has an increased risk of oral clefts (cleft lip with or without cleft palate) according to data from pregnancy registries and epidemiology studies
- Qsymia is contraindicated in pregnancy (Pregnancy Category X)

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Recommendations to mitigate the risk of teratogenicity in females of reproductive potential taking Qsymia®

- Females of reproductive potential should have a negative pregnancy test before starting Qsymia and monthly thereafter during Qsymia therapy
- Females of reproductive potential should 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 apprised of the potential hazard to the fetus

Patient counseling regarding the risk of teratogenicity associated with Qsymia therapy

- Advise females of reproductive potential to use effective contraception consistently while taking Qsymia because Qsymia can cause certain kinds of birth defects (oral clefts). Even females who believe they cannot become pregnant should use effective contraception consistently while taking Qsymia
- Inform patients who become pregnant while taking Qsymia to discontinue Qsymia immediately, and contact you for further follow-up

Qsymia Healthcare Provider Training Program
Training, support, and additional information about the increased teratogenic risk are available for prescribers. Visit www.QsymiaREMS.com to take the prescriber training program.

Dispensing by 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. Qsymia is now available through certified retail pharmacies in addition to certified mail order pharmacies. The list of certified pharmacies can be found at www.QsymiaREMS.com.

Reporting adverse events
Healthcare providers should report all suspected adverse events associated with the use of Qsymia. If you become aware of a patient experiencing an adverse event while taking Qsymia, please contact VIVUS Medical Information at 1-888-998-4887 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the accompanying Qsymia Prescribing Information, Qsymia Medication Guide, *Risk of Birth Defects with Qsymia* patient brochure, and Dear Healthcare Provider Letter. For more information, visit www.QsymiaREMS.com or call VIVUS Medical Information at 1-888-998-4887.

Sincerely,

Santosh T. Varghese, MD
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