Risk Evaluation and Mitigation Strategy (REMS) Document
Qsymia (phentermine and topiramate extended-release) Capsules
REMS Program

I. Administrative Information

Application Number: NDA 22580
Application Holder: VIVUS LLC
Initial REMS Approval: 07/2012
Most Recent REMS Update: 03/2022

II. REMS Goal

To inform certified pharmacies and patients of reproductive potential about:

1. The increased risk of congenital malformations, specifically orofacial clefts, in infants exposed to Qsymia during the first trimester of pregnancy
2. The importance of pregnancy prevention for patients of reproductive potential receiving Qsymia
3. The need to discontinue Qsymia immediately if pregnancy occurs

III. REMS Requirements

VIVUS LLC must ensure that pharmacies and wholesalers-distributors comply with the following requirements:

1. Pharmacies that dispense Qsymia must:

   To become certified to dispense

   1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.
   2. Have the authorized representative successfully complete the Pharmacy Training Program and submit it to the REMS Program.
   3. Have the authorized representative enroll in the REMS Program on behalf of the pharmacy by completing and submitting the Pharmacy Enrollment Form to the REMS Program.
   4. Train all relevant staff involved in dispensing on the risks associated with Qsymia and requirement to provide the Medication Guide and Risk of Birth Defects with Qsymia using the Pharmacy Training Program.
   5. Establish processes and procedures to provide the Medication Guide and the Risk of Birth Defects with Qsymia to each patient each time Qsymia is dispensed.
Before dispensing

6. Provide the patient with the Medication Guide and the Risk of Birth Defects with Qsymia through the processes and procedures established as a requirement of the REMS Program.

At all times

7. Not distribute, transfer, loan, or sell Qsymia.
8. Maintain records of standard operating procedures, training, and providing the Medication Guide and the Risk of Birth Defects with Qsymia.
9. Maintain and submit annual compliance reports to the REMS Program.
10. Comply with audits carried out by VIVUS LLC to ensure that all processes and procedures are in place and are being followed.

2. Wholesalers-distributors that distribute Qsymia must:

To be able to distribute

1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies.

At all times

2. Distribute only to certified pharmacies.
3. Maintain and submit annual compliance reports of adherence to distribution requirements of the REMS Program.

VIVUS LLC must provide training to pharmacies who dispense Qsymia.

The training includes the following educational material: Pharmacy Training Program. The training must be available online and hard copy by mail or fax.

To support REMS Program operations, VIVUS LLC must:

1. Establish and maintain a REMS website, www.qsymiarems.com. The REMS website must include the capability to complete pharmacy certification online, to locate certified pharmacies, and the option to print the Prescribing Information, Medication Guide, and REMS materials. The product website for consumers and healthcare providers must include prominent REMS-specific links to the REMS website. The REMS website must not link back to the promotional product website.
2. Make the REMS website fully operational and all REMS materials available through the website within 90 calendar days of REMS modification.
3. Establish and maintain a REMS support center for REMS participants at 1-888-998-4887 and a Pharmacy support center for pharmacists at 1-855-302-6698.
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the Qsymia REMS Program.
5. Ensure pharmacies are able to become certified online and by phone.
6. Provide the Pharmacy Training Program and the Prescribing Information to pharmacies who (1) attempt to dispense Qsymia and are not yet certified or (2) inquire about how to become certified.
7. Notify pharmacies within 2 business days after they become certified in the REMS Program.
8. Provide authorized wholesalers-distributors access to the database of certified pharmacies.

**To ensure REMS participants’ compliance with the REMS Program, VIVUS LLC must:**

9. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: Qsymia distribution and dispensing; certification of pharmacies, and audits of REMS participants. These records must be readily available for FDA inspections.

10. Establish a plan for addressing noncompliance with REMS Program requirements.

11. Monitor pharmacies and wholesalers-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.

12. Audit certified pharmacies no later than 180 calendar days after they become certified and a representative sample of certified pharmacies every two years, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.

13. Take reasonable steps to improve implementation of and compliance with the requirements in the Qsymia REMS Program based on monitoring and evaluation of the Qsymia REMS Program.

**IV. REMS Assessment Timetable**

VIVUS LLC must submit REMS Assessments at 6 months and 12 months from the date of initial approval of the REMS and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. VIVUS LLC must submit each assessment so that it will be received by the FDA on or before the due date.

**V. REMS Materials**

The following materials are part of the Qsymia REMS:

**Enrollment Forms**

Pharmacy

1. Independent Pharmacy Enrollment Form
2. Corporate Entity of Retail Chain Pharmacy Enrollment Form
3. Mail Order Pharmacy Enrollment Form

**Training and Educational Materials**

Pharmacy:

4. Pharmacy Training Program

Patient:

5. Medication Guide
6. Risk of Birth Defects with Qsymia

**Other Materials**

7. REMS Program Website

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