



### ***Risk of Birth Defects with Qsymia®*** **(phentermine and topiramate extended-release) capsules CIV**

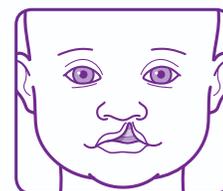
**Please read the following important safety information about the use of Qsymia in females who can become pregnant.**

You are considered a female 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



**cleft lip**

#### **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**

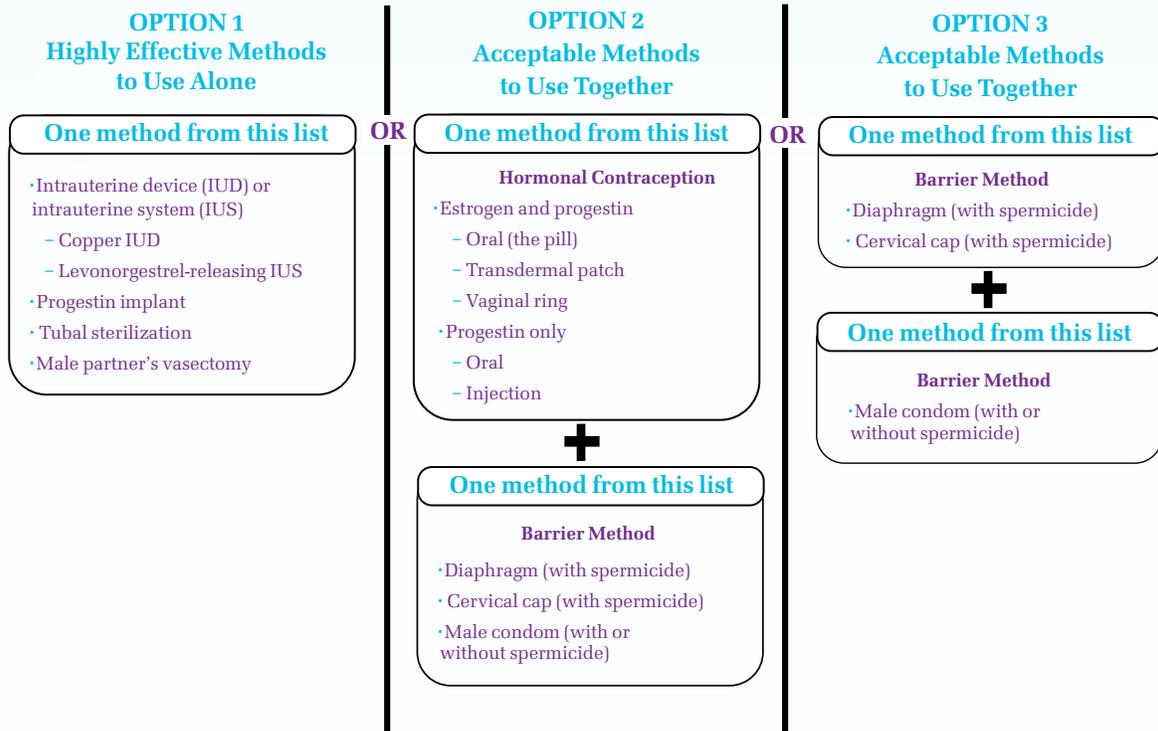
- Certain birth control methods are effective when used alone. Other birth control methods are not as effective by themselves, so you should use a second method of birth control

**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.**



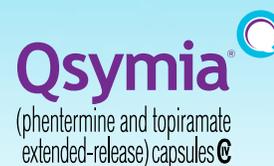
## Your Birth Control Options



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](http://www.QsymiaREMS.com).





## Healthcare Provider Counseling Tool for Females of Reproductive Potential

Use this counseling tool to discuss the increased risk of teratogenicity associated with the use of Qsymia® with your patients, and the important steps that should be taken to minimize the risk of fetal exposure.

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**Females of reproductive potential are women 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.**

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**The following points should be reviewed and discussed with all females of reproductive potential:**

- **Qsymia can increase the risk of congenital malformations, specifically orofacial clefts**
  - Advise patients that orofacial clefts (cleft lip and cleft palate) occur early in pregnancy, at ~5 to 6 weeks gestation (post-conception), which may be before a patient realizes she is pregnant
- **Effective methods of contraception should be used consistently during treatment with Qsymia**
  - Advise patients that they should consistently use effective methods of contraception while taking Qsymia
  - The table on the back provides effective methods of contraception to review and discuss with your patient
  - Consider referral to a gynecologist if additional counseling or contraceptive selection is required
- **Pregnancy testing is recommended before initiating treatment with Qsymia and monthly during treatment**
  - Advise patients to undergo pregnancy testing before starting Qsymia and monthly thereafter. Discuss with patients whether pregnancy testing should be performed in the office or with a home pregnancy test
  - Advise patients that if they have a positive pregnancy test initially, they will not be prescribed Qsymia, and if they are already taking Qsymia and realize they are pregnant, they must stop it immediately and report the pregnancy to you
- **Review the *Risk of Birth Defects with Qsymia* patient brochure and the *Qsymia Medication Guide* with your patient. Provide these documents to your patient**



### Acceptable Contraception Methods for Females of Reproductive Potential

