

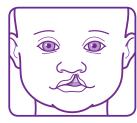
## Risk of Birth Defects with Qsymia®

(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 birth defects including:
  - Cleft lip and cleft palate (as shown in the picture)
  - Your baby may also be smaller than expected at birth; the long-term effects of this are not known
  - 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**

## OPTION 1 Highly Effective Methods to Use Alone

#### One method from this list

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

# OPTION 2 Acceptable Methods to Use Together

#### One method from this list

#### **Hormonal Contraception**

OR

- · Estrogen and progestin
  - Oral (the pill)
  - Transdermal patch
  - Vaginal ring
- · Progestin only
- Oral

OR

- Injection

## +

#### One method from this list

#### **Barrier Method**

- · Diaphragm (with spermicide)
- · Cervical cap (with spermicide)
- Male condom (with or without spermicide)

### OPTION 3 Acceptable Methods to Use Together

#### One method from this list

#### **Barrier Method**

- · Diaphragm (with spermicide)
- · Cervical cap (with spermicide)



#### One method from this list

#### **Barrier Method**

 Male condom (with or without 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 Website www.QsymiaREMS.com.

