



This information has been gathered by The Cleft Lip & Palate Foundation of Smiles. We are responding to the fact that a number of our members have questions concerning the safety of medications that they had taken during pregnancy, or may take during a future pregnancy. These medications may be the cause of craniofacial differences. Our goal is to ensure that our families have resources and facts about the medications that may be taken during pregnancy, so you can have informed discussions with the treating doctors.

Online at www.cleftsmile.org

Contact us by email at rachel@cleftsmile.org

The Cleft Lip & Palate Foundation of Smiles provides research on craniofacial causes (genetics, environmental, prescription drugs), treatments (cleft palate teams, medical devices, therapies), and available support for families.

Causes of Cleft Lip and Palate: QSYMIA

What is Qsymia?

Qsymia is a prescription weight loss medicine for adults who are obese or overweight with weight-related medical problems such as high blood pressure or type 2 diabetes. The drug is intended for adults with a body mass index (BMI) of 30 or higher, or for those with weight-related medical issues, 27 or higher.

Qsymia is known as a Pregnancy Category X drug. The FDA assigns approved drugs to pregnancy categories to identify drugs that may have additional risks for newborns. They base the decision for each drug on data from animal studies and clinical studies or experience, as it is unethical

to perform clinical studies on pregnant women. Pregnancy categories are useful tools for patients and healthcare professionals to weigh the risks and benefits of using a drug during pregnancy. The risk of consuming drugs in Pregnancy Category X during pregnancy clearly outweigh the benefits. For these medications, healthcare providers should advise either a safe delay in treatment or an alternative medication.

According to the drug's website, "Qsymia can harm your unborn baby. If you take Qsymia while you are pregnant, your baby has a higher risk for birth defects called cleft lip and cleft palate. These defects can begin early in pregnancy, even before you know you are pregnant."



Who makes Qsymia?

Vivus, a small pharmaceutical company based in California, manufactures Qsymia. Vivus develops products for obesity, sexual health and sleep.

What are phentermine and topiramate?

Qsymia contains the drugs phentermine and topiramate in extended-release form. Phentermine is generally used for short-term weight loss in overweight or obese adults, in addition to exercise and a healthy diet. Because it contains phentermine, Qsymia is a federally controlled substance (CIV) and can be abused or lead to drug dependence.

Topiramate, the generic version of Topamax, is used to treat certain types of epileptic seizures and to prevent migraine headaches.

Anti-epileptic drugs (AEDs) such as topiramate pose concerns about possible teratogenicity, an agent that causes malformation of a fetus. Topiramate has been associated with severe eye problems such as sudden decrease in vision and glaucoma. These side effects can lead to permanent vision loss. The drug also increases the risk of suicidal thoughts.

A fetus exposed to topiramate in the first trimester of pregnancy has an increased risk of a cleft lip and/or cleft palate. Women of childbearing years must not be pregnant or become pregnant when taking Qsymia. Women should have a negative pregnancy test before starting Qsymia and every month while taking the drug, and they should consistently use effective contraception during this time.

More resources are available.

For further questions about cleft lip and cleft palate, contact The Cleft Lip and Palate Foundation of Smiles. Cleft lip and palate are two of the most common birth defects, which affect one in 600 children in the United States. The Foundation was formed by a young mother of twins born with cleft lip and palate. The Foundation offers positive support to parents of children with craniofacial differences by offering news, information on cleft palate teams, state by state resources, birth registry listings, and a support group where you can meet other families who are going through similar concerns, and where you can share and express useful information.

References

FDA approves weight-management drug Qsymia. [FDA News Release](#). July 17, 2012.

Prescriptions for contraindicated category X drugs in pregnancy among women enrolled in TennCare. William O. Cooper, Gerald B. Hickson and Wayne A. Ray. ©Blackwell Publishing Ltd. *Paediatric and Perinatal Epidemiology* 2004, **18**, 106–111. [Posted on FDA](#).

[Qsymia Medication Guide](#). ©2012, VIVUS, Inc.

For more information, including current news about Qsymia, visit the community run forums at www.qsymia-diet-drug.com.

QSYMIA (phentermine and topiramate) Extended-release Capsules [Category: anorectic and antiepileptic] VIVUS, Inc. [RISK EVALUATION AND MITIGATION STRATEGY \(REMS\)](#).

