

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.

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.

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

