Risk Evaluation and Mitigation Strategy (REMS)

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of a drug outweigh its risks. The FDA has required a REMS for Qsymia.

The purpose of the Qsymia REMS is to inform prescribers and females of reproductive potential about the:
- Increased risk of congenital malformation, specifically orofacial clefts, in infants exposed to Qsymia during the first trimester of pregnancy.
- Importance of pregnancy prevention for females of reproductive potential receiving Qsymia.
- Need to discontinue Qsymia immediately if pregnancy occurs.

Healthcare Provider Training Program

The Qsymia REMS includes a healthcare provider training program.

Counseling Females on Risk of Birth Defects with Qsymia

- Counsel females of reproductive potential at initial and all follow-up visits on the increased risk of orofacial clefts in infants exposed to Qsymia during the first trimester of pregnancy.
- Counsel females of reproductive potential to have a pregnancy test before starting Qsymia and monthly thereafter during therapy.
- Discuss the need for consistent use of effective contraception during therapy.
- Make use of the REMS tools supporting patient education that are available on this website.

Dispensed to Patients Through Certified Pharmacies

Qsymia is available only through certified pharmacies. Click Here to learn more.