# Risk Category for Drugs in Pregnancy

The FDA has established five categories to indicate the potential of a drug to cause birth defects. Category differentiation depends on reliability of documentation.

**Category A:**

Adequate studies in pregnant women have not demonstrated a risk to the fetus in the first trimester, nor is there evidence of risk in later trimesters.

**Category B:**

Animal studies have not demonstrated a risk to the fetus, but there are no adequate studies in pregnant women. Or, animal studies have shown an adverse effect, but adequate studies in pregnant women have not demonstrated a risk to the fetus in the first trimester, and there is no evidence of risk to the fetus in later trimesters.

**Category C:**

Animal studies have shown an adverse effect on the fetus, but there are no adequate studies in pregnant women. Benefits for the use of the drug by pregnant women may outweigh the potential risks.

**Category D:**

There is positive evidence of human fetal risks, but the benefits may outweigh the potential risks to the fetus.

**Category X:**

Studies in animals and humans demonstrated fetal abnormalities. The risks to the fetus clearly outweigh any possible benefit to the pregnant women.