

## Classification of Drug Related Risks in Pregnancy

**Class A** - adequate & well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in 1st trimester of pregnancy and no evidence of risk in later trimesters.

**Class B** - animal studies have failed to demonstrate a risk to the fetus but there are no well-controlled studies in pregnant women; or animal reproduction studies have shown an adverse effect.

**Class C** - animal studies have shown adverse effect on fetus but no well-controlled studies in humans: potential benefits may warrant use in pregnant women despite potential risks; or no animal reproduction studies and no adequate and well-controlled studies in humans.

**Class D** - positive evidence of human fetal risk based on investigation or marketing information but potential benefits may warrant use of drug in pregnant women despite potential risks.

**Class X** - studies in animals or humans have shown fetal abnormalities and/or there is positive evidence of fetal risk based on investigational or marketing information and risks involved in use of drug in pregnant women clearly outweigh potential benefits.