Risk Factors

Risk Factors (A, B, C, D, X) have been assigned to all drugs, based on the level of risk the drug poses to the fetus. Risk Factors are designed to help the reader quickly classify a drug for use during pregnancy. They do not refer to breast-feeding risk. Because they tend to oversimplify a complex topic, they should always be used in conjunction with the Fetal Risk Summary. The definitions for the Factors are those used by the Food and Drug Administration (Federal Register 1980;44:37434-67). Since most drugs have not yet been given a letter rating by their manufactures, the Risk Factor assignments were usually made by the authors. If the manufacturer rated its product in its professional literature, the Risk Factor on the monograph will be shown with a subscript M (e.g., $C_{M)}$. If the manufacturer and the authors differed in their assignment of a Risk Factor, our Risk Factor is marked with an asterisk and the manufacture's rating is shown at the end of the amides, morphine, etc.) are drugs that present different risks to the fetus, depending on when or for how long they are used. In these cases, a second Risk Factor will be found with a short explanation at the end of the Fetal Risk Summary. We hope this will increase the usefulness of these ratings. The definitions used for the Risk Factors are presented below.

Category A: Controlled studies in women fail to demonstrate a risk to the fetus in the first trimester (and there is no evidence of a risk in later trimesters), and the possibility of fetal harm appears remote.

Category B: Either animal-reproduction studies have not demonstrated a fetal risk but there are no controlled studies in pregnant women or animal-reproduction studies have shown an adverse effect (other than a decrease in fertility) that was not confirmed in controlled studies in women in the first trimester (and there is no evidence of a risk in later trimesters).

Category C: Either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal, or other) and there are no controlled studies in women or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Category D: There is positive evidence of human fetal risk, but the benefits from use in pregnant women may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

Category X: Studies in animals or human beings have demonstrated fetal abnormalities, or there is evidence of fetal risk based on human experience, or both, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.