

FDA PREGNANCY CATEGORIES

When pregnancy appears as a contraindication or precaution to the use of a drug, it is usually qualified by a category as assigned by the FDA.

- A:** Adequate and well-controlled studies in pregnant women have failed to show a risk to the fetus in the first trimester of pregnancy and there is no evidence of risk in later trimesters.
 - B:** Animal studies have failed to show a risk to the fetus and there are no adequate and well-controlled studies in pregnant women; or animal studies have shown an adverse effect but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester of pregnancy and there is no evidence of a risk in later trimesters.
 - C:** Animal studies have shown an adverse effect on the fetus, there are no adequate and well-controlled studies in humans, and the potential benefits may outweigh the risks; or there are no animal studies and no adequate and well-controlled studies in humans.
 - D:** Positive evidence of human fetal risk but the benefits may outweigh the risks.
 - X:** Animal or human studies have shown fetal abnormalities or toxicity, or both, and the risks clearly outweigh any possible benefits.
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