

Pregnancy Categories

<u>Category</u>	<u>Definitions*</u>	<u>Clinical Application</u>
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 trimester), and the possibility of fetal harm appears remote."	For all practical purposes, there are no Category A drugs.
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 B drugs include prenatal vitamins, acetaminophen and several other medications used routinely and safely during pregnancy. If there is a clinical need for a Category B drug, it is considered safe to use it.
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 C drugs have <u>not</u> been shown to be harmful to fetuses (if they had been, they wouldn't be Category C drugs). However, there are some reasons to be more concerned about these drugs than Category B drugs. If the pregnant patient will benefit from a Category C drug, it is generally used, although most obstetricians would prefer a Category B drug if it will give equivalently good results.
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 D drugs have some significant risks. They should be used during pregnancy only when the alternatives are worse.
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."	Category X drugs should not be used during pregnancy.

*Food and Drug Administration. Federal Register 1980;44:37434-67

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