
FDA PREGNANCY CATEGORIES

The FDA-assigned pregnancy categories as used in the Drug Formulary are as follows:

Category A

Adequate and well-controlled studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters).

Category B

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

Category C

Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Category D

There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Category X

Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.

MEDICATION EXPOSURES DURING PREGNANCY AND LACTATION

Every woman in the general population has a 3–5% risk of having a child with a birth defect or mental retardation. Birth defects are the leading cause of infant mortality in the United States. Two important factors to consider when assessing the teratogenic potential of a medication are the stage of pregnancy at which the exposure occurred and the amount of medication taken. It is critical to evaluate each exposure on a case-by-case basis in order to give an accurate risk assessment.

Some of the known, possible, and unlikely human teratogens are listed below. If you have a pregnant or breast feeding patient who is currently taking, or considering taking, a medication, the patient needs to be counseled about potential adverse effects the medication could have on her fetus or infant. This counseling needs to be documented in the patient's chart.

CARE (Counseling and Advice on Reproductive Exposures) Northwest provides health care professionals and patients with comprehensive up-to-date information on the potential risks associated with exposure to drugs and chemicals during pregnancy and lactation. *CARE* Northwest serves to bridge the gap between an often conflicting and limited body of published literature and the practitioner who must respond to patients' concerns about drug exposures during pregnancy. In-clinic evaluations can be requested for complex cases and written risk assessments are available for inclusion in the patient's medical record when warranted.

UWMC and HMC practitioners can access a trained counselor at *CARE* Northwest by dialing toll-free (888) 616-8484.

Some Known Teratogens

- **Radiation**
 - Atomic weapons
 - Radioiodine
 - Therapeutic radiation
- **Infections**
 - Cytomegalovirus
 - Herpes simplex virus I and II
 - Parvovirus B-19 (Erythema infectiosum)
 - Rubella virus
 - Syphilis
 - Toxoplasmosis
 - Varicella virus
 - Venezuelan equine encephalitis virus
- **Maternal & Metabolic Imbalance**
 - Alcoholism
 - Amniocentesis, early (before day 70 post conception)
 - Chorionic villus sampling (before day 60 post conception)
 - Cretinism, endemic
 - Diabetes
 - Folic acid deficiency
 - Hyperthermia
 - Myasthenia gravis
 - Phenylketonuria
 - Rheumatic disease
 - Sjögren's syndrome
 - Virilizing tumors

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Some Known Teratogens

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• Drugs and Environmental Chemicals

ACE inhibitors (benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, trandolapril)
 Aminopterin
 Androgenic hormones
 Busulfan
 Chlorobiphenyls
 Cigarette Smoking
 Cocaine
 Coumarin anticoagulants
 Cyclophosphamide
 Diethylstilbestrol
 Etretinate
 Fluconazole (high doses)
 Iodides
 Isotretinoin (Accutane®)
 Lithium
 Mercury, organic
 Methimazole
 Methotrexate (methylaminopterin)
 Methylene blue (via intraamniotic injection)
 Misoprostol
 Penicillamine
 Phenytoin
 Tetracyclines
 Thalidomide
 Toluene (abuse)
 Trimethadione
 Valproic acid

Possible Teratogens

Binge drinking
 Carbamazepine
 Colchicine
 Disulfiram
 Ergotamine
 Glucocorticoids
 Lead
 Primidone
 Quinine (suicidal doses)
 Streptomycin
 Vitamin A (high doses)
 Zidovudine (AZT)
 Zinc deficiency

Unlikely Teratogens

Agent Orange
 Anesthetics
 Aspartame
 Aspirin (but aspirin in the 2nd half of pregnancy may increase cerebral hemorrhage during delivery)
 Bendectin® (antinauseant)
 Electromagnetic waves
 Hydroxyprogesterone
 LSD
 Marijuana
 Medroxyprogesterone
 Metronidazole
 Oral contraceptives
 Progesterone
 Rubella vaccine
 Spermicides
 Video display terminals
 Ultrasound

For more information contact:
 CARE Northwest
 or the
 UW Drug Information Center