



Psychopharmacology TIDBITS

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-TB- Pregnancy Risk Categorization.

The decision to use psychopharmaceutical interventions in pregnant female patients can be challenging. Often, a risk benefit assessment is helpful when identifying possible care interventions. Pharmacotherapy is an option when non-pharmacological interventions are ineffective or inappropriate. Decisions regarding the appropriateness of drug selection require careful thought by both the provider and patient. The FDA has established five categories (A, B, C, D and X) that indicate a drug's potential for causing teratogenicity.

FDA Pregnancy Risk Categories

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.

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).

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.**

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).

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.

Common Pregnancy Risk Categories for Psychotropic Medications

DRUG	PREGNANCY CATEGORY	COMMENTS ON BREAST FEEDING/LACTATION
ANTIDEPRESSANTS		
Amitriptyline (Elavil)	C/D	<i>Effect unknown</i>
Doxepin (Sinequan)	C	<i>Breastfeeding is unsafe</i> Poor sucking and swallowing, muscle hypotonia, drowsiness, vomiting, and jaundice occurred in a neonate whose mother used DOXEPIIN in her third trimester and during the postpartum period.
Imipramine (Tofranil)	D	The amount of IMIPRAMINE and DESIPRAMINE available to an infant is small. The amount of IMIPRAMINE measured in breast milk was 4 to 29 ng/mL and DESIPRAMINE was 17 to 35 ng/mL
Citalopram (Celexa)	C	Two cases of infants experiencing excessive somnolence, decreased feeding, and weight loss have been reported.
Fluoxetine (Prozac)	C	<i>Breastfeeding is not recommended.</i> Despite a limited number of reports of fluoxetine use during breastfeeding, the American Academy of Pediatrics classifies fluoxetine as a drug whose effect on nursing infants is unknown, but may be of concern. Infant exposure to fluoxetine via breast milk ranges from 3.3% to 10%.
Fluvoxamine (Luvox)	C	<i>Effect unknown.</i> Even though reports of adverse effects in breast-fed infants are lacking, the American Academy of Pediatrics classifies fluvoxamine as a drug that may be of concern in infants
Paroxetine (Paxil)	C	<i>Effects unknown</i>
Sertraline (Zoloft)	C	<i>Effects unknown</i> Non-quantifiable (0 ng/mL to 2 ng/mL) concentrations of sertraline were detected in 7 of 9 infants
MOOD STABILIZERS		
Carbamazepine (Tegretol)	D	<i>Breastfeeding is considered safe.</i> Breastfed newborns have developed serum carbamazepine levels between 15% to 65% of maternal levels
Lithium (Lithobid, Eskalith)	D	<i>Breastfeeding is considered unsafe.</i> Lithium can be detected in breast milk in concentrations of 0.16 to 0.56 milliequivalents/liter, which represents 33 to 50% of the corresponding lithium serum level
Valproic Acid (Depakote)	D	<i>Breastfeeding is considered safe.</i> Breast milk levels have ranged from 1% to 10% of the maternal serum level.

ANTIPSYCHOTICS		
Haloperidol (Haldol)	C	<i>Breastfeeding is controversial.</i> Concentrations of up to 23.5 ng/mL have been reported in breast milk
Fluphenazine (Prolixin)	C	<i>Breastfeeding is considered safe.</i> Phenothiazines do not accumulate in concentrations high enough to produce clinical adverse effects in breast-fed infants
Perphenazine (Trilafon)	C	<i>Breastfeeding is unsafe</i>
Thioridazine (Mellaril)	C	<i>Effect unknown</i>
Chlorpromazine (Thorazine)	C	<i>Breastfeeding is controversial</i> Metabolites do not accumulate in concentrations high enough to produce clinical adverse effects in the infant
Clozapine (Clozaril)	B	<i>Breastfeeding is not recommended</i> Breast-feeding during clozapine treatment is not recommended; clozapine has been detected in breast milk in animal studies
Olanzapine (Zyprexa)	C	<i>Effects unknown</i>
Quetiapine (Seroquel)	C	<i>Effects unknown</i> Women receiving Seroquel are advised not to breast feed
Risperidone (Risperdal)	C	<i>Breastfeeding is controversial</i> Data from 1 report show that the distribution of risperidone and 9-hydroxyrisperidone into breast milk is modest.
Ziprasidone (Geodon)	C	<i>Effect unknown</i>
