

## APPENDIX IV

### DRUGS AND PREGNANCY

Drugs can have harmful effects on mother and foetus at any time during pregnancy. Use of medications during pregnancy requires a careful assessment of risks and benefits for them. During the first trimester, teratogenic effects are frequent. There is higher risk from third to eleventh weeks of gestation. During the second and third trimester, drugs may affect the growth and functional development of foetus or have toxic effect on the foetal tissues. Drugs administered shortly before term or during labour may have adverse effect on mother or on neonate. The FDA has established five categories (A, B, C, D, X) which indicate the potential of a systemically absorbed drugs causing birth defects. These categories are indicative of the level of risk to the foetus. The category X includes the drugs for which there are enough data to implicate their teratogenicity and the risk vs. benefit ratio does not support the use of the drug and hence these are contraindicated during pregnancy. A few drugs present variable risk to the foetus depending on the time and duration of their use. These drugs have been assigned double categories. The categories of risk involved are as under:

**A:** Adequate studies in pregnant women have not demonstrated a risk to the foetus in the first trimester of pregnancy and there is no evidence of risk in later trimesters.

**B:** Animal studies have not demonstrated a risk to the foetus but there are no adequate studies in pregnant women or, animal studies have shown an adverse effect, but adequate studies in pregnant women have not demonstrated a risk to the foetus during the first trimester of pregnancy and there is no evidence of risk in later trimesters.

**C:** Animal studies have shown an adverse effect on the foetus but, there are no adequate studies in humans or there are no animal reproduction studies and no adequate studies in humans; the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks.

**D:** There is evidence of human foetal risk, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks.

**X:** Studies in animals or humans demonstrate foetal abnormalities or adverse reaction reports indicate evidence of foetal risk; the risk of use in a pregnant woman clearly outweighs any possible benefits.

Drugs	Categories	Drugs	Categories
<b>1. Anaesthetics</b>		<b>3. Antiallergic and drugs used in anaphylaxis</b>	
<b>General anaesthetics</b>		Cetirizine	B
Ether	D	Chlorpheniramine maleate	B
Fentanyl	B/D	Cinnarizine	C
Halothane	A/D	Dexamethasone sodium phosphate	C
Isoflurane	C	Epinephrine hydrochloride	C
Ketamine hydrochloride	A/D	Hydrocortisone acetate	C
Nitrous oxide	D	Pheniramine maleate	C
Propofol	B	Prednisolone	B
Sodium thiopentone	B	Promethazine	C
<b>Local anaesthetics</b>		<b>4. Antidotes and other substances used in poisoning</b>	
Bupivacaine hydrochloride	C	Activated charcoal powder	A/B
Lignocaine hydrochloride	A/C	Antisnake venom	C/D
Lignocaine with adrenaline	C	Desferrioxamine	C
<b>Preoperative medication and sedation for short-term procedures</b>		Dimercaprol	D/X
Atropine sulphate	C	Disodium calcium edetate	D
Chloral hydrate	C	Methylene blue	C/D
Diazepam	D	Naloxone	B
Midazolam	D	PAM	C
Morphine sulphate	B/D	Penicillamine	D
Promethazine	C	Sodium nitrite	D
<b>2. Analgesics, antipyretics and drugs for gout</b>		Sodium thiosulphate	C
Acetyl salicylic acid	C/D	<b>5. Antiepileptic drugs</b>	
Allopurinol	C	Carbamazepine	C
Diclofenac sodium	B	Clonazepam	C
Dihydroergotamine mesylate	D	Lamotrigine	C
Ibuprofen	B/D	Phenobarbitone	D
Indomethacin	B/D	Phenytoin sodium	D
Mefenamic acid	C	Sodium valproate	D
Morphine sulphate	B/D	<b>6. Anti-infective drugs</b>	
Paracetamol	B	<b>Intestinal anthelmintics</b>	
Pentazocine lactate	B/D	Albendazole	D/X
Pethidine hydrochloride	B/D	Mebendazole	C
Probenecid	B	Praziquantel	B/D
Tramadol	C	Pyrantel pamoate	C
<b>Drugs for migraine</b>			
Dihydroergotamine	X		

Drugs	Categories	Drugs	Categories
<b><i>Antifilarials</i></b>		Quinine dihydrochloride	C
Diethylcarbamazine	X	Quinine sulphate	C
		Roxithromycin	B
<b><i>Antibacterials, antivirals, antifungals, antiprotozoals</i></b>		Sulfadoxine + Pyrimethamine	D
Acyclovir	C	Sulfamethoxazole + Trimethoprim	C
Amikacin	C	Tetracycline	D
Amoxicillin	B	Tinidazole	D/X
Amphotericin B	B	Trimethoprim	C
Ampicillin	B	Vancomycin	C
Carbenicillin	B	Zidovudine	C
Cefotaxime	B		
Ceftazidime	B	<b><i>Antileprosy drugs</i></b>	
Ceftriaxone	B	Clofazimine	C
Cefuroxime	B	Dapsone	C
Cephalexin	B		
Chloramphenicol	C	<b><i>Antitubercular drugs</i></b>	
Chloroquine phosphate	C	Ethambutol	B
Cinnarizine	C	Isoniazid	C
Ciprofloxacin	C	Pyrazinamide	C
Cloxacillin	B	Rifampicin	C
Diloxanide furoate	D	Streptomycin	D
Doxycycline	D		
Erythromycin	B	<b>7. Antiparkinsonism drugs</b>	
Fluconazole	C	Bromocriptine	C
Gentamicin	C	Levodopa + Carbidopa	C/D
Griseofulvin	C	Selegiline	C
Indinavir	C	Trihexyphenidyl	C
Ketoconazole	C		
Lamivudine	B	<b>8. Drugs affecting blood</b>	
Meropenem	B	<b><i>Anti-anaemic drugs</i></b>	
Metronidazole	B	Ferrous fumarate	A
Nalidixic acid	B	Ferrous sulphate	A
Nevirapine	C	Folic acid	A/C
Norfloxacin	C	Iron dextran	C
Ofloxacin	C		
Penicillin benzathine	B	<b><i>Drugs affecting coagulation</i></b>	
Penicillin crystalline	B	Dalteparin	B
Penicillin procaine	B	Enoxaparin	B
Piperacillin	B	Heparin	C
Primaquine	C	Protamine sulphate	C

Drugs	Categories	Drugs	Categories
Vitamin K	C	Simvastatin	X
Warfarin	D		
<b>9. Blood products and substitutes</b>		<b>Drugs used in vascular shock and peripheral vascular diseases</b>	
Dextran-40	C	Dobutamine	C
Dextrose 5%+Sodium chloride	C	Dopamine	C
Polymer from degraded gelatin + electrolytes made isotonic solution	C	Mephentermine	C
<b>10. Cardiovascular drugs</b>		<b>11. Dermatological drugs</b>	
<b>Antianginal drugs</b>		<b>Antifungal drugs</b>	
Atenolol	C	Benzoic acid + Salicylic acid	C
Glyceryl trinitrate	C	Clotrimazole	B/C
Isosorbide dinitrate	C	Miconazole	C
Isosorbide mononitrate	C	Nystatin	B/C
Metoprolol	B	<b>Anti-infective drugs</b>	
Propranolol	C	Framycetin	C
<b>Antidysrhythmic drugs</b>		Povidone iodine	D
Adenosine	C	Silver nitrate	C
Amiodarone	C	Silver sulfadiazine	C
Diltiazem	C	<b>Scabicides and pediculocides</b>	
Disopyramide	C	Benzyl benzoate	B
Lignocaine	A/C	Gamma benzene hexachloride	B
Mexiletine	C	Permethrin	B
Procainamide	C	<b>Anti-inflammatory and antipruritic drugs</b>	
Verapamil	C	Betamethasone	C
<b>Antihypertensive drugs</b>		Clobetasol	C
Amlodipine	C	<b>Keratoplastic and keratolytic agents</b>	
Enalapril	C/D	Benzoyl peroxide	C
Felodipine	C	Coal tar	C
Hydralazine	C	Podophyllin	X
Indapamide	D	Salicylic acid	C
Methyldopa	C	<b>Ultraviolet blocking agents</b>	
Nifedipine	C	5-Methoxy psoralen	C
Sodium nitroprusside	C	Para-amino benzoic acid	C
<b>Cardiac glycosides</b>		Trimethyl psoralen	C
Digoxin	C	<b>Others</b>	
<b>Hypolipidaemic drugs</b>		Tretinoin	C
Fenofibrate	C	Triamcinolone	C

Drugs	Categories	Drugs	Categories
<b>12. Diagnostic agents</b>		<b><i>Anti-inflammatory drugs</i></b>	
<b><i>Oral contrast agents</i></b>		5-Amino salicylic acid	B
Calcium iopodate	D	Dicyclomine	B
<b><i>Intravascular contrast agents</i></b>		Hyoscine butyl bromide	C
Meglumine diatrizoate	D	Sulfasalazine	B/D
Meglumine iothalamate	D	<b><i>Cathartic drugs</i></b>	
Sodium diatrizoate and meglumine diatrizoate	D	Bisacodyl	C
Sodium iothalamate	D	Lactulose	B
<b>13. Disinfectants and antiseptics</b>		<b><i>Drugs used in diarrhoea</i></b>	
Acriflavin + Glycerine	C	Furazolidone	C
Cetrimide + Chlorhexidine	B	<b>16. Hormones, other endocrine drugs and contraceptives</b>	
Spirit	C	<b><i>Pituitary hormone</i></b>	
<b>14. Diuretics</b>		Octreotide	B
Frusemide	C	<b><i>Adrenal hormones and synthetic substitutes</i></b>	
Glycerol	C	Prednisolone	B/C
Hydrochlorothiazide	D	Methylprednisolone	C
Mannitol	C	sodium succinate	
Spironolactone	D	<b><i>Androgens</i></b>	
<b>15. Gastrointestinal drugs</b>		Nandrolone decanoate	X
<b><i>Antacids and other antiulcer drugs</i></b>		<b><i>Contraceptives</i></b>	
Cisapride	C	Ethinyl oestradiol + Levonorgestrel	X
Magnesium hydroxide + Aluminium hydroxide + Activated methyl polysiloxone	B	Ethinyl oestradiol + Norethisterone	X
Mosapride	C	<b><i>Oestrogens</i></b>	
Omeprazole	C	Conjugated equine oestrogen	X
Ranitidine	B	Ethinyl oestradiol	X
Sucralfate	B	<b><i>Progesterogens</i></b>	
<b><i>Antiemetic drugs</i></b>		Danazol	X
Metoclopramide	B	Medroxy progesterone acetate	D
Desmopressin	B	Norethisterone	X
<b><i>Antihaemorrhoidal drugs</i></b>		<b><i>Insulin and other antidiabetic drugs</i></b>	
Betamethasone valerate + Lignocaine + Phenylephrine	C	Insulin lente	B
		Insulin semilente	B
		Metformin	C
		Tolbutamide	D

Drugs	Categories	Drugs	Categories
Glibenclamide	D	Methylergometrine maleate	D
Insulin	B	Methyl PGF <sub>2α</sub>	C
<b>Drugs affecting calcification and bone turnover</b>		Oxytocin	A
Alendronate	C		
<b>Thyroid hormones and antithyroid drugs</b>			
Carbimazole	D	<b>21. Psychotherapeutic drugs</b>	
Iodine	D	Alprazolam	D
Thyroxine sodium	A	Amitriptyline	D
		Chlorpromazine	C
<b>17. Immunological agents</b>		Clozapine	B
Anti-rabies (vero cells)	C	Diazepam	D
Hepatitis	B	Fluoxetine	B
MMR (live vaccine) USP	X	Fluphenazine	C
Measles IP	X	Haloperidol	C
Meningococcal poly-saccharide vaccine	C	Imipramine hydrochloride	D
Monoclonal anti-Rh (D)-immunoglobulin	A	Lithium carbonate	D
Rubella (live vaccine) BP	X	Lorazepam	D
Typhoid IP	C	Nitrazepam	D
BCG (freeze dried) IP	C	Risperidone	C
DT (adsorbed) IP	C	Thioridazine	C
Poliomyelitis IP	C	Trazodone	C
Tetanus toxoid	A	Trifluoperazine	C
<b>18. Muscle relaxant and anticholinesterase</b>		<b>22. Drugs acting on respiratory system</b>	
Atracurium	C	Aminophylline	C
Methocarbamol	X	Beclomethasone	C
Neostigmine	C	Budesonide	C
Pancuronium	C	Etiophylline + theophylline	C
Suxamethonium	C	Ipratropium bromide	B
Vecuronium	C	Salbutamol	C
		Terbutaline	B
		<b>Antitussives</b>	
		Bromhexine hydrochloride	A
		Codeine phosphate	C/D
		Diphenhydramine	B
<b>19. Oxytocics and antioxotocics</b>		<b>23. Solution correcting water electrolyte</b>	
Dinoprostone	C	Calcium chloride, USP	C
Isoxsuprine	C	Calcium gluconate	C
Magnesium sulphate	B	Dextran	C

<b>Drugs</b>	<b>Categories</b>	<b>Drugs</b>	<b>Categories</b>
Dextrose	C	Dexamethasone + Neomycin	C
Isolyte	C	Ketorolac	C
N/2 & N/4 dextrose with normal saline	C	<b>Miotics and antiglaucoma drugs</b>	
N/6 Normal saline	C	Pilocarpine	C
Potassium chloride	C	Timolol	C
Ringer lactate	C	<b>Mydriatics</b>	
Sodium bicarbonate	C	Atropine	C
Sodium chloride	C	Cyclopentolate	C
Sodium chloride, USP	C	Homatropine	C
<b>24. Vitamins and minerals</b>		Phenylephrine	C
Calcium carbonate	A/C	Tropicamide	C
Calcium gluconate	C	<b>Others</b>	
Pyridoxine	A/C	Acetazolamide	C
Vitamin A	A/X	Fluorescein	C
Vitamin B Complex NFI	A/C	Hyaluronidase	C
Vitamin B <sub>1</sub>	A/C	Hydroxypropyl methylcellulose	C
Vitamin B <sub>12</sub>	A/C	Proparacain	C
Vitamin C	A/C	<b>27. Anticancer drugs</b>	
Vitamin D <sub>3</sub>	A/D	Asparaginase	C
<b>25. Dental preparations</b>		Bleomycin	D
Povidone iodine	D	Busulfan	D
Salicylate, Gel	C	Calcium Folinic acid	C
<b>26. Ophthalmological preparations</b>		Cisplatin	D
<i>Anti-infective agents</i>		Cyclophosphamide	D
Acyclovir	C	Cyclosporine A	D
Chloramphenicol	C	Cytosine arabinoside	D
Ciprofloxacin	C	Daunomycin	D
Framycetin	C	Doxorubicin	D
Gentamicin	C	Etoposide	D
Miconazole	C	5-fluorouracil	D
Natamycin	C	GMCSF	C
Oxytetracycline	D	Melphalan	D
Sulfacetamide	B/D	Mercaptopurine	D
Tobramycin	B	Methotrexate	D
<i>Anti-inflammatory agents</i>		Paclitaxel	D
Dexamethasone	C	Procarbazine	D
Dexamethasone + Gentamicin	C	Tamoxifen	D
		Vinceristine	D

Drugs	Categories	Drugs	Categories
<b>28. Solutions for parenteral nutrition</b>		<b>29. ENT drugs</b>	
Amino acid solution for parenteral nutrition		Gentamicin + betamethasone	C
Fat emulsion for parenteral nutrition		Chloramphenicol	C
Human normal serum albumin		Clotrimazole, Eardrops	B
B		Gentamicin, Eardrops	C
		Glucose in glycerine	C
		Sodabicarb glycerine	C
		Xylometazoline nasal drops	C

**Note:** The table should be used as a guide; absence from the table does not imply safety.

### References

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