

Drug Use in Pregnancy and Lactation Summary Table

KTPH Pharmacy Dept

Important note:

1. For all female patients under 50 years of age, ask if patient is pregnant or breastfeeding. Check which trimester patient's pregnancy is in, and age of the breast-feeding baby where applicable.
2. Information in the remarks column should be used more for making interventions with doctors, not for informing patients. Do not reveal details because when taken out of context, it can cause unnecessary alarm in patients.
3. Drugs are arranged within each class in order of their safety for use in pregnancy and lactation.
4. In cases where the pregnancy category is C or "risk cannot be ruled out", and you are unsure, call the Pharmacist on-call at 9855 0620.

US FDA Pregnancy Category Definitions

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 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.
"M"	Subscript "M" after a Pregnancy Category denotes recommendation by manufacturer e.g B _M or C _M

Others:

Compatible	Either the drug is not excreted in clinically significant amounts into human breast milk or its use during lactation does not, or is not expected to, cause toxicity in nursing infant.
Risk cannot be ruled out	Avoid when possible. View "Remarks" and weigh risk vs benefit. Contact pharmacist if unsure.
Avoid	Drugs are classified in this way if they can have dangerous side-effects on the baby. They should not be given to a mother while she is breastfeeding. If they are essential for treating the mother, she should stop breastfeeding until treatment is completed. If treatment is prolonged, she may need to stop breastfeeding altogether. There are very few drugs in this category apart from anticancer drugs and radioactive substances.

Painkillers: Non-NSAIDs

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Paracetamol	B	Paracetamol is commonly used in all stages of pregnancy. There does not appear to be any risk to the embryo or fetus from the maternal use of therapeutic doses. (Briggs, FDA)	Compatible	Safest painkiller
Paracetamol + orphenadrine (Anarex)	C	Limited human data, no relevant animal data. (Briggs, FDA)	Risk cannot be ruled out	Until more data are available, use with caution when considering the use of orphenadrine in lactating women.
Tramadol	C	Human data suggest risk in 3 rd trimester. Chronic use during pregnancy may lead to physical dependence & postpartum withdrawal symptoms in neonates. (Briggs, AHFS)	Risk cannot be ruled out	Both tramadol and its M1 active metabolite are excreted in breast milk following intravenous dosing. However, the effects on the nursing infant from exposure to the drug are unknown.
Codeine	C – check duration and dose (see below)	Human data suggest risk in 3 rd trimester. If used for prolonged periods or in high doses at term, associated with birth defects, neonatal respiratory depression and withdrawal. (Briggs, Drugdex)	Compatible	In nursing mothers, select the lowest dose for the shortest amount of time and closely monitor mother-infant pairs.
	D (in prolonged use or high doses at term)			

Painkillers: NSAIDs

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Ibuprofen (Nurofen®)	B (2 nd trimester)	Human data suggest risk in 1 st and 3 rd trimester.	Compatible	Ibuprofen is undetectable in breast milk and would therefore be an option in nursing mothers.
	D (1 st & 3 rd trimesters)			
Mefenamic acid (Ponstan®)	C	Human data suggests risk in 1 st and 3 rd trimester.	Compatible	Small amounts of the drug were detected in the breast milk. No significant adverse effects were noted in the infants.
Naproxen (Synflex®)	C	Human data suggest risk in 1 st and 3 rd trimester.	Compatible	Although naproxen appears in breast milk, the concentration is too low to be pharmacologically significant.

Etoricoxib (Arcoxia®)	C_m	Potential for human risk in pregnancy unknown.	Avoid	Manufacturer: Not known whether excreted in human milk but present in animal studies.
Diclofenac	C (1st & 2nd trimesters)	Exposure during the 1 st trimester is not strongly associated with congenital malformations, however it may cause premature closure of the ductus arteriosus in late pregnancy. (FDA)	Avoid	Low concentrations of diclofenac can be found in breast milk. Breastfeeding is not recommended by the manufacturer. (FDA)
	D (3rd trimester)			

“m” denotes recommendation by manufacturer.

Runny nose and blocked nose

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Loratadine (Clarityne®) Cetirizine (Zyrtec)	B	Limited human data. Animal data suggest low risk. (Briggs, AHFS)	Compatible	Based on the usual recommended oral dose of 10 mg per day, it is unlikely that an exposed infant would be seriously affected by the small amount in breast milk.
Chlorpheniramine (Piriton®)	B	Because of risk of severe reactions to antihistamines in neonates, should not be used during 3 rd trimester. (Briggs, AHFS)	Avoid	Use of chlorpheniramine in nursing mothers should be avoided if possible. Nursing infants of mothers treated with chlorpheniramine (sedating antihistamine) should be monitored for possible side effects, including drowsiness and irritability.
Diphenhydramine (Benadryl®)	B	Drug of choice if parenteral antihistamines are indicated in pregnancy. All suggest safe except a case-control study showing association with cleft palate. (Briggs, FDA)	Avoid	Diphenhydramine is contraindicated and should not be used by nursing mothers.
Oxymetazoline (nasal spray)	Risk cannot be ruled out	Oxymetazoline is absorbed systemically after topical administration. Adverse fetal or neonatal effects have not been observed following normal maternal doses of oxymetazoline during the third trimester of pregnancy. Adverse effects have been noted in case reports following large doses or extended use. (FDA)	Risk cannot be ruled out	Until more data is available, use caution when considering the use of oxymetazoline in lactating women.
Promethazine	C	Safe use not established, should be used only when potential benefits justify the possible risks to the fetus. (Briggs, AHFS)	Risk cannot be ruled out	Until more data is available, use caution when considering the use of promethazine in lactating women. Nursing infants of mothers treated with promethazine (sedating antihistamine) should be monitored for drowsiness.
Loratadine + pseudoephedrine	X	Avoid use due to limited human data. Ephedrine, a similar medication, can cause constriction of	Avoid	Pseudoephedrine distributes into breast milk of lactating human females, with drug

(Clarinase®)		uterine vessels, which results in fetal hypoxia. (Briggs, Drugdex)		concentrations in milk consistently higher than those in plasma. Symptoms of excessive stimulation in a breastfeeding infant have been observed; therefore nursing infants of mothers taking pseudoephedrine should be monitored for these symptoms.
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Cough: productive

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Bromhexine (Bisolvon®)	B	No data. Until more information is available, should only be used if the maternal condition justifies the potential risk to the fetus. (ADEC, Drugdex)	Risk cannot be ruled out	No studies available on the use of bromhexine during lactation or the effects of drug exposure through the milk on nursing infants.
Diphenhydramine expectorant (contains Ammonium Cl)	B	Infant risks cannot be ruled out. All suggest safe except a case-control study showing association with cleft palate. (Briggs, FDA)	Avoid	Antihistamines pose a potential harm to nursing infants; diphenhydramine is contraindicated and should not be used by nursing mothers.
Guaifenesin (Robitussin EX®)	C	No data on the use of guaifenesin in pregnant women.	Risk cannot be ruled out.	It is not known if guaifenesin affects the quantity and composition of breast milk.

Cough: non-productive

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Dextromethorphan	A	Dextromethorphan formulations that do not contain ethanol are thought to be safe for use during both pregnancy and breastfeeding.	Compatible	Dextromethorphan formulations that do not contain ethanol are thought to be safe for use during both pregnancy and breastfeeding.

Sore throat

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Chlorhexidine mouthwash	B	Chlorhexidine was not teratogenic in rat studies.	Risk cannot be ruled out	No reports available and effects on the nursing infant from exposure to the drug in milk are unknown.
Dequalinium lozenges	N/A	Manufacturer: Safety for use in pregnancy and nursing mothers not established.	N/A	Manufacturer: Safety for use in pregnancy and nursing mothers not established.
Benzydamine lozenges (Difflam®)	N/A	Manufacturer: Safety for use in pregnancy and nursing mothers not established.	N/A	Manufacturer: Safety for use in pregnancy and nursing mothers not established.

Diarrhea

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Loperamide (Imodium®)	B	Poorly absorbed from the gut. Available data indicate it presents a minimum risk of malformations when used during pregnancy.	Compatible	Negligible amounts of the drug would be expected to be excreted in breast milk.
Charcoal (ultracarbon®)	Risk cannot be ruled out	Not absorbed from GIT and not expected to produce a problem during pregnancy and lactation.	Risk cannot be ruled out	Not absorbed from GIT and not expected to produce a problem during pregnancy and lactation.
Diphenoxylate + atropine (Lomotil®)	C	Limited human data. Animal data suggest low risk. (Briggs, FDA)	Risk cannot be ruled out	The major metabolite of diphenoxylate, diphenoxylate acid, may be excreted into breast milk. Atropine is excreted into breast milk. Suggest loperamide as an alternative for nursing mothers.
Kaolin	N/A	No data. Not absorbed from GIT and not expected to produce a problem during pregnancy.	N/A	Prolonged, chronic use in the mother may lead to anemia, which could adversely affect the quality of breast milk.

Stomach cramps / spasm

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Hyoscine butylbromide (Buscopan®)	C	Long experience has shown no evidence of ill-effects during pregnancy. Use only if potential benefit outweighs risk. (Manufacturer, BNF)	Compatible	The American Academy of Pediatrics considers scopolamine to be usually compatible with breastfeeding although it enters breast milk.

Gastric – Antacid (components), PPIs and H₂ antagonist

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Magnesium carbonate	A	Minimal absorption, likely safe for both pregnancy and lactation.	N/A	Minimal absorption, likely safe for both pregnancy and lactation.
Magnesium trisilicate	A	Minimal absorption, likely safe for both pregnancy and lactation.	N/A	Minimal absorption, likely safe for both pregnancy and lactation.
Famotidine	B	Inadequate controlled studies, should be used during pregnancy only when clearly needed. (Briggs, AHFS)	Risk cannot be ruled out	Amount excreted into human breast milk is clinically insignificant as it is less than the maximum dosage for a child younger than 1 year old.

Lansoprazole (Prevacid®)	B	No human data, animal data suggest low risk. (Briggs, AHFS)	Risk cannot be ruled out	It is unknown whether lansoprazole is excreted in human milk. No studies investigating the use of lansoprazole in breastfeeding women have been located.
Omeprazole (Losec®)	C	Although adverse effects of congenital abnormalities have been reported in humans, a direct cause and effect relationship have not been proven.	Risk cannot be ruled out	Possibly excreted into human milk, not recommended for breastfeeding mothers.

Nausea and vomiting

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Domperidone (Motilium®)	C	No human data – animal data suggest risk. Severe dose-related toxicity reported in adults. (Briggs, FDA)	Compatible	A small amount is excreted into breast milk. There were no reported side effects in the nursing infants attributable to domperidone.
Metoclopramide (Maxolon®)	B	No congenital malformations or other fetal or newborn adverse effects attributable to metoclopramide. (Briggs, FDA)	Risk cannot be ruled out	Studies showed amount of metoclopramide excreted into breast milk is less than recommended therapeutic dose for children.
Prochlorperazine	C	Majority of evidence indicate prochlorperazine & general class of phenothiazines are safe. Lowest effective dose should be used. (Briggs, Drugdex)	Risk cannot be ruled out	Limited studies have suggested a possible relationship between phenothiazine use in infants and sudden infant death syndrome.
Promethazine	C	Limited evidence, safe use not established. (Briggs, AHFS)	Risk cannot be ruled out	The World Health Organization considers promethazine compatible with breastfeeding if given in a single dose ; avoid giving repeated doses and monitor the infant for drowsiness.

Topical steroids - Should not be used on extensive areas, in large amounts or for prolonged periods.

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Hydrocortisone	A	Hydrocortisone is enzymatically inactivated in the placenta, thereby limiting fetal exposure.	Risk cannot be ruled out	It is unknown whether topically administered corticosteroids are present in high enough systemic concentrations to be found in breast milk. Avoid using on extensive areas, in large amounts or for prolonged periods.

Betamethasone (Betnovate®)	C	Systemic absorption of topical corticosteroids has produced reversible neuroendocrine suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients, and these could pose a risk in pregnancy.	Risk cannot be ruled out	Topically applied betamethasone is considered compatible with breastfeeding by the WHO.
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Antibiotics – Penicillins - In general, penicillins are considered safe for use in pregnancy. A causal relationship between cephalosporins and teratogenic effects has not been found.

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Amoxicillin	B	Penicillins are generally considered to be safe for use in patients during pregnancy. (Briggs, Drugdex)	Compatible	Although amoxicillin does appear in breast milk, the concentration is too low to be clinically significant.
Amoxicillin + clavulanic acid (Augmentin®)	B_m	No adverse effects to the fetus in study with limited number of pregnant women. No clear evidence of teratogenicity in rodent studies.	Compatible	Distributed into milk, use with caution in nursing mothers.
Cloxacillin	B	Inadequate controlled studies. However, no evidence of adverse effects to fetus. (Briggs, Drugdex)	Compatible	No reports describing the use of cloxacillin during human lactation are available and the effects on the nursing infant from exposure to the drug in milk are unknown.

Antibiotics – Cephalosporins - In general, cephalosporins are considered safe for use in pregnancy. A causal relationship between cephalosporins and teratogenic effects has not been found.

Antibiotics – Macrolides

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Erythromycin ethylsuccinate	B	Shown to cross the placental barrier; however, fetal plasma levels were low.	Compatible	Diarrhea, vomiting, and irritability have also been reported in a case series of infants exposed to erythromycin through breast milk.
Clarithromycin (Klacid®)	C	Adverse effects in pregnancy including cardiovascular anomalies, cleft palate and fetal growth retardation have been reported in animal studies.	Risk cannot be ruled out	It is not known whether clarithromycin or its metabolites are excreted into human breast milk and the potential for adverse effects in the nursing infant from exposure to the drug are unknown.

Antibiotics – Fluoroquinolones

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Ciprofloxacin	C	Ciprofloxacin does not appear to be a major human teratogen when used at therapeutic doses. Caution in 1 st trimester. Use safer alternatives if possible.	Compatible	Ciprofloxacin is excreted into human breast milk. The estimated amount potentially ingested by a nursing infant appears low. However adverse effects could be serious.

Antibiotics – Tetracyclines - All tetracyclines cross the placenta and are known to cause a yellow or brown-gray to black discoloration of the deciduous teeth of children born to mothers who received the drug during the second and third trimester of pregnancy.

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Doxycycline	D	Contraindicated in 2 nd and 3 rd trimesters due to risk of teratogenic effects reported throughout pregnancy. (Briggs, Drugdex)	Risk cannot be ruled out	The manufacturer suggests that due to the potential for serious adverse reactions in nursing infants from doxycycline, the risks and benefits of therapy must be assessed. Either nursing or doxycycline should be discontinued.

Antibiotics – Aminoglycosides - Aminoglycoside antibiotics cross the placenta. Cases of irreversible bilateral congenital deafness have been reported in children whose mothers received aminoglycosides during pregnancy

Antibiotics – Miscellaneous

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Clindamycin	B	A causal relationship between clindamycin and teratogenic effects has not been found.	Risk cannot be ruled out	Although one case of bloody stools in a breastfeeding infant has been reported in association with maternal use of clindamycin, a causal relationship remains to be established.
Metronidazole	B (2nd & 3rd trimester) D (1st trimester)	Contraindicated during the first trimester of pregnancy.	Risk cannot be ruled out	Secreted in human breast milk at similar concentrations as those found in plasma.

Viral infection

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Acyclovir	B	Reported pregnancy outcomes after human exposure to systemic acyclovir do not indicate an increased risk of birth defects. (Briggs, Drugdex)	Compatible	Although acyclovir is concentrated in breast milk, concentrations are considered clinically unimportant.

Fungal infection - WHO: Topical preparations are not usually absorbed in significant amounts and can usually be used safely during pregnancy. Clotrimazole or miconazole would be logical first-line agents for fungal infections of the skin during pregnancy.

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Clotrimazole	B (topical and vaginal)	Topical clotrimazole is considered to be safe for use during pregnancy.	Risk cannot be ruled out	It is not known if clotrimazole affects the quantity and composition of breast milk.
	C (systemic)			
Itraconazole (Sporal®)	C	A causal relationship between itraconazole and teratogenic effects has not been found.	Risk cannot be ruled out	In animal studies, the drug accumulates in fatty tissues, and repeated oral doses could lead to clinically significant milk levels.
Ketoconazole (Nizoral®)	C	Adverse effects were noted in animal reproduction studies with oral ketoconazole. No adequate and well-controlled studies of the use of ketoconazole during pregnancy in humans. Ketoconazole is not detectable in the plasma following chronic use of the shampoo. (FDA)	Risk cannot be ruled out	Not known whether topical ketoconazole is systemically absorbed in sufficient quantities to produce detectable levels in breast milk.
Miconazole	C (systemic)	Topical miconazole cream and vaginal suppositories used in pregnant women resulted in no teratogenic effects.	Risk cannot be ruled out	The WHO considers topical miconazole compatible with breastfeeding.
Nystatin	C	Poorly absorbed orally. Limited human data show no association with congenital defects. (Briggs, ADEC)	Risk cannot be ruled out	Effects on the nursing infant from exposure to the drug in milk are unknown.

Eye/ear irritation - Occlusion of the nasal puncta during administration of eyedrops is recommended to reduce possibility of systemic absorption.

Antimicrobial, antifungal and immunosuppressant eye/ear drops

Drug	Pregnancy Category	Remarks	Lactation	Remarks
Cefazolin 50mg/ml Eyedrop 10ml	B	There are no well-controlled studies of cefazolin use in pregnant women. However, no detectable teratogenic risk with cephalosporin antibiotics was found in a large study. (Briggs, Drugdex)	Compatible	Although cefazolin appears in breast milk in small amounts, the concentration is too low to be clinically important.
Gentamicin Eye Drop 0.3%w/v 5 ml; Fortified Gentamicin 14mg/ml	D	Due to reports of fetal ototoxicity (including deafness) with other aminoglycosides, use of gentamicin is not recommended during pregnancy. (FDA, Drugdex)	Compatible	Gentamicin is generally considered safe for use during breastfeeding. Even though gentamicin appears in the breast milk, it is unlikely that adverse effects in the infant would develop.
Tetracycline 1% ointment	D	Contraindicated in 2 nd & 3 rd trimesters. Adverse effects on fetal teeth and bones, maternal liver toxicity and congenital defects. (Briggs, Drugdex)	Compatible	Although the reported oral bioavailability is moderately high, it is suspected that calcium present in the breast milk binds the tetracycline thereby preventing its absorption by the infant.
Chloramphenicol 0.5%w/v Eyedrop	C	Little data. Administration near term may result in the development of "gray-baby syndrome" & possible infant death due to cardiovascular collapse. (Briggs, Drugdex)	Risk cannot be ruled out	Chloramphenicol is not contraindicated during breastfeeding, but the infant should be monitored for early signs of a severe reaction including hemolysis and jaundice.
Fluorometholone 0.1% (FML [®] eye drop)	Risk cannot be ruled out	Fluorometholone has demonstrated teratogenicity and embryoletality in rabbits receiving low multiples of the human ocular dose.	Risk cannot be ruled out	Lack of data on the use of fluorometholone during lactation.
Fusidic Acid 1% 5ml (Fucithalmic [®])	Risk cannot be ruled out	Manufacturer: Animal studies and many years of clinical experience have suggested that fusidic acid is not teratogenic.	Risk cannot be ruled out	No reports, effects unknown. Until more data are available, use with caution. (ADEC, Drugdex)
Moxifloxacin 0.5% Eye Drop 5ml	C	There is insufficient clinical experience with moxifloxacin in pregnancy to confirm its safety. Quinolones are not recommended for general use due to the possibility of teratogenic effects as suggested by animal studies. (Briggs, Drugdex)	Risk cannot be ruled out	Moxifloxacin has been detected in the milk of lactating rats, but it is unknown if moxifloxacin is excreted in human breast milk.
Framycetin + Dexamethasone + Gramicidin (Sofradex [®] Ear/Eye Drop)	D	Manufacturer: Safety for use in pregnancy and lactation has not been established. Topical administration of corticosteroids to pregnant animals can cause abnormalities of fetal development and growth retardation.	Risk cannot be ruled out	Manufacturer: Safety for use in pregnancy and lactation has not been established.
Tobramycin + dexamethasone (Tobradex [®])	D	Corticosteroids have been found to be teratogenic in animal studies.	Avoid	Not known whether this drug is excreted in human milk.

Prepared by: Drug Information, Pharmacy Department

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