



Pregnancy Safety Index

Based on available
Generics in Bangladesh



Pregnancy Safety Index

Based on available Generics in Bangladesh

2nd Edition' 2015

Published in January' 2015

Compiled & Published by
Product Management Department

Design and Graphics by
DTP, Marketing Division



Pregnancy Category ¹

The pregnancy category of a pharmaceutical agent is an assessment of the risk of fetal injury due to the pharmaceutical agents, if it is used as directed, by the mother during pregnancy. It does not include any risks conferred by pharmaceutical agents or their metabolites that are present in breast milk.

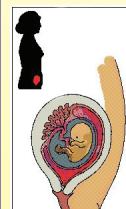
How does a medicine affect the developing baby? ²

Drugs that a pregnant woman takes can affect the fetus in several ways. They can act directly on the fetus causing damage or abnormal development leading to birth defects or death. They can also alter the function of the placenta usually by constricting blood vessels and reducing the blood supply of oxygen and nutrients to the fetus from the mother and thus resulting in a baby that is underweight and underdeveloped. Moreover they can cause the muscles of the uterus to contract forcefully; indirectly injuring the fetus by reducing the blood supply or triggering pre-term labor and delivery.

First Trimester of Pregnancy

First trimester (0 to 12 weeks)

The first trimester is the period of greatest risk for the baby. This is because during this stage the baby's organs are developing. Medicines taken during this time have the potential to affect this development, which could result in malformations or birth defects. If a defect is very severe this could cause a miscarriage.



Second Trimester of Pregnancy

Second trimester (13 to 28 weeks)

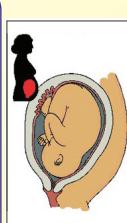
During the second trimester medicines can interfere with the development of the baby's nervous system, or with the growth of the baby, resulting in a low birth weight. However, generally, experts believe that the second trimester is the safest period to take medicines.



Third Trimester of Pregnancy

Third trimester (29 to 40 weeks)

Medicines taken in the final three months of pregnancy can cause complications such as breathing difficulties for the baby after birth. This is because the medicine remains in the baby's body after birth, and the newborn baby may not be able to cope with the medicine in its bloodstream the way the mother can.



Classification of Pregnancy category of drugs from different countries^{1,3}



United States

In 1979, the United States Food and Drug Administration (FDA) introduced a classification of fetal risks due to pharmaceutical agents.

The United States FDA has the following definitions for the pregnancy categories:

United States FDA Pharmaceutical Pregnancy Categories	
Pregnancy 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."
Pregnancy 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)."
Pregnancy 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."
Pregnancy 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.)"
Pregnancy 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."

One characteristic of the FDA definitions of the pregnancy categories is that the FDA requires a relatively large amount of high-quality data on a pharmaceutical agents for it to be defined as Pregnancy Category A. As a result of this, many drugs that would be considered Pregnancy Category A & B in other countries are allocated to Category C by the FDA.



Australia⁴

Australia has a slightly different pregnancy category system from the United States - notably the subdivision of Category B. The system, as outlined below, was established by the Congenital Abnormalities Sub-committee of the Australian Drug Evaluation Committee (ADEC).

ADEC Pregnancy Categories (Australia)

Pregnancy Category A

Drugs that have been taken by a large number of pregnant women and women of childbearing age without an increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Pregnancy Category B1

Drugs that have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have not shown evidence of an increased occurrence of fetal damage.

Pregnancy Category B2	Drugs that have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.
Pregnancy Category B3	Drugs that have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals have shown evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.
Pregnancy Category C	Drugs that, owing to their pharmaceutical effects, have caused - or may be suspected of causing - harmful effects on the human fetus or neonate without causing malformations.
Pregnancy Category D	Drugs that have caused, are suspected to have caused or may be expected to cause an increased incidence of human fetal malformations. These drugs may also have adverse pharmacological effects.
Pregnancy Category X	Drugs that have such a high risk of causing permanent damage to the fetus that they should not be used in pregnancy or when there is a possibility of pregnancy.

The subcategorization of Category B, while offering additional information that may be of benefit in evaluating the risk vs benefit, presents its own problem of data reliability - since human data is lacking or inadequate, the subcategorization is based on animal data. Furthermore, allocation of a drug in Category B does not necessarily imply greater safety than Category C.

Drugs in Category D are not absolutely contraindicated in pregnancy, unlike those of Category X. In some cases, Category D was assigned to a drug on the basis of suspicion.

Categorization of selected agents

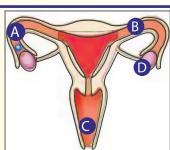
Classification of some agents based on different national bodies

Pharmaceutical agents	FDA(United States)	Australia
Acetaminophen/Paracetamol	B	A
Acetylsalicylic acid/Aspirin	D	C
Amoxicillin	B	A
Amoxicillin with clavulanic acid	B	B
Cefotaxime	B	B
Diclofenac	C	C
Leflunomide	X	X
Loperamide	B	B
Paroxetine	D	D
Phenytoin	D	D
Rifampicin	C	C
Thalidomide	X	X
Theophylline	C	A
Tetracycline	D	D
Triamcinolone (skin)	C	A

*Disclaimer: The data presented is for comparative and illustrative purposes only and may have been superseded by updated data.

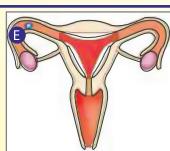
The female monthly cycle⁵

1



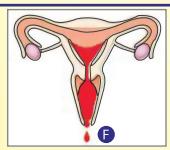
- A Egg being released
- B Fallopian tube
- C Vagina
- D Ovary

2



- E Egg progressing down the fallopian tube

3



- F Uterus lining being shed

Ovulation occurs each month when an egg (ovum) is released from one of the ovaries. Occasionally, more than one egg is released, usually within 24 hours of the first egg. The 'fingers' at the end of the fallopian tubes help to direct the egg down into the tube. At the same time, the lining of the uterus begins to thicken and the mucus in the cervix becomes thinner so that sperm can swim through it more easily.

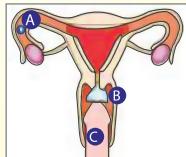
The egg begins to travel down the fallopian tube. If a man and woman have recently had sex, the egg might be fertilised here by the man's sperm. The lining of the uterus is now thick enough for the fertilised egg to be implanted.

If the egg is not fertilised, it will pass out of the body during the woman's monthly period along with the lining of the uterus, which is also shed. The egg is so small that it cannot be seen.

Conception

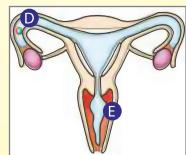
Conception is the process that begins with the fertilisation of an egg and ends with the implantation of an egg into a woman's uterus.

1



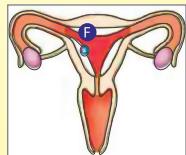
- A Egg
- B Sperm being ejaculated
- C Penis

2



- A Egg being fertilised
- B Sperm

3



- A Attached embryo

Ovulation

A woman conceives around the time when she is ovulating; that is, when an egg has been released from one of her ovaries into one of her fallopian tubes.

Fertilisation

During sex, sperm are ejaculated from a man's penis into a woman's Vagina. In one ejaculation there may be more than 300 million sperm. Most of the sperm leak out of the Vagina but some begin to swim up through the cervix. When a woman is ovulating, the mucus in the cervix is thinner than usual to let sperm pass through more easily. Sperm swims into the uterus and into the fallopian tubes. Fertilisation takes place if a sperm joins with an egg and fertilises it.

Implantation

During the week after fertilisation, the fertilised egg (which is now an embryo) moves slowly down the fallopian tube and into the uterus. It is already growing. The embryo attaches itself firmly to the specially thickened uterus lining. This is called implantation. Hormones released by the embryonic tissue prevent the uterus lining from being shed. This is why women miss their periods when they are pregnant.

Clinical trials on human of Cefuroxime for pregnancy category⁶

In one study of seven pregnant women, cefuroxime 750 mg intravenously one to eight hours before delivery revealed passage of the drug across the placenta. The average maternal plasma, amniotic fluid, umbilical cord, and neonatal plasma cefuroxime levels ranged from 0 to 24, 1.2 to 18.0, less than 2.0 to 11.0, and less than 2.0 to 3.6 mcg per ml, respectively. No adverse effects on the fetus or neonates were observed.

In one study of 78 pregnant women between 15 to 35 weeks' gestation who were given cefuroxime 750 mg intravenously 8 to 138 minutes prior to delivery, the average fetal plasma levels were 7.4 mcg per ml (normal fetuses), 6.2 mcg per ml (hydropic fetuses), and 4.9 mcg per ml (oligohydramniotic fetuses). These data show that Transplacental passage is significantly reduced in the presence of oligohydramnios. Incidentally, the plasma clearance of cefuroxime is significantly increased and the elimination half-life significantly decreased during pregnancy.

Cefuroxime has been assigned to pregnancy category B by the FDA. Animal studies failed to reveal evidence of fetal harm. Cefuroxime should only be given during pregnancy when need has been clearly established.

Clinical trials on human of Meclizine for pregnancy category⁶

In a study 613 mothers were given meclizine during the first trimester for the control of nausea and vomiting. No increase in the incidence of malformations was noted. In addition, other phenothiazine-type agents used for nausea including prochlorperazine and cyclizine were not associated with malformations. The Collaborative Perinatal Project monitored 50,282 mother-child pairs, of which 1014 were exposed to meclizine during the first 16 weeks of pregnancy. The standardized relative risk was not elevated for meclizine use and malformations overall.

Meclizine has been assigned to pregnancy category B by the FDA. Although meclizine has been shown to be teratogenic in animals, studies of meclizine use in the first trimester of human pregnancy found no increase in the rate of malformations. Meclizine is only recommended for use during pregnancy when benefit outweighs risk.

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Acarbose		Per Oral	B
Acetobutolol		Per Oral	B; D in 2 nd & 3 rd trim.
Acetazolamide		Per Oral	C
Acyclovir	Acerux®	Per Oral	B
		Parenteral	B
		Topical	B
		Per Oral	B
		Topical	C
Acrivastine		Parenteral	C
Adapalene		Per Oral	C
Adenosine		Per Oral	C
Albendazole		Per Oral	C
Alfuzosin		Per Oral	B
Allopurinol	Duric®	Per Oral	C
Alprazolam		Parenteral	C
Amantadine	Alprax®	Per Oral	D
Ambroxol HCl		Per Oral	C
Amikacin	Boxol®	Patenteral	D
Amiloride		Per Oral	B
Aminophylline		Per Oral	C
Amiodarone		Parenteral	C
Amitriptyline		Rectal	C
Amlodipine	Filin®	Per Oral	D
Amoxicillin		Parenteral	D
Ampicillin	Amilin®	Per Oral	C
Antazoline		Parenteral	C
Aripiprazole	Amocal®	Per Oral	C
Aspartame		Per Oral	C
Aspirin	Moxin®	Per Oral	B
Atenolol		Per Oral	C
	Ampexin®	Ophthalmic	C
		Per Oral	B
	Aripen®	Per Oral	C
		Per Oral	B
	Solrin®	Per Oral	C
		Per Oral	D
	Betasec®	Per Oral	C
		Per Oral	D

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Atomoxetine		Per Oral	C
Atorvastatin		Per Oral	X
Atropine		Ophthalmic	C
Azathioprine		Per Oral	D
Azelastine	Zelanex®	Parenteral	D
Azithromycin		Ophthalmic/Nasal	C
	Azicin®	Per Oral	B
		Parenteral	B
Bacitracin		Ophthalmic	C
		Parenteral	C
		Topical	C
Baclofen	Beklo®	Per Oral	C
Beclometasone		Parenteral	C
Benazepril		Inhalation/ Nasal	C
Benzocaine		Per Oral	C; D in 2 nd & 3 rd trim
Benzyl Penicillin		Mouth/Throat	C
Betacarotene		Parenteral	B
Betamethasone	Pen G®	Per Oral	A; X if dose>US RDA
		Per Oral	C; D in 1 st trimester
	Betson®	Parenteral	C; D in 1 st trimester
		Topical	C; D in 1 st trimester
Betaxolol		Ophthalmic	C
		Per Oral	C; D in 2 nd & 3 rd trim
Bisacodyl	Duralax®	Per Oral	B
Bisoprolol	Bislol®	Rectal	B
Brimonidine	Bricoma®	Per Oral	C; D in 2 nd & 3 rd trim
Brinzolamide	Xolamid®	Ophthalmic	B
Bromocriptine	Bromodel®	Ophthalmic	C
		Per Oral	B
		Inhalation	B
Budesonide	Pulmicort®	Nasal	B
		Per Oral	C
		Rectal	C

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Bumetanide		Per Oral	C
Bupivacaine		Parenteral	C
Busulfan		Parenteral	C
Caffeine		Per Oral	D
Calcipotriol		Per Oral	B
Calcitriol	Improcal®	Topical	C
Calcium	Ostogen®	Per Oral	C; D if dose > US RDA
Calcium acetate	Calci®	Parenteral	C; D if dose > US RDA
Capecitabine		Per Oral	B
Captopril		Per Oral	C
Carbamazepine	Cazep®	Per Oral	D
Carbidopa		Per Oral	C; D in 2 nd & 3 rd trim
Carbimazole		Per Oral	D
Carbinoxamine		Per Oral	C
Carvedilol	Cardex®	Per Oral	C; D in 2 nd & 3 rd trim
Cefaclor	Clobac®	Per Oral	B
Cefadroxil	Trubid®	Per Oral	B
Cefalexin		Per Oral	B
Cefazolin		Parenteral	B
Cefdinir		Per Oral	B
Cefipime	Xenim®	Parenteral	B
Cefixime	Ceftid®	Per Oral	B
Cefotaxime	Ceftax®	Parenteral	B
Cefpodoxime	Rovantin®	Per Oral	B
Cefprozil		Per Oral	B
Cefradine	Cephran®	Per Oral	B
Ceftazidime	Serozid®	Parenteral	B
Ceftibuten		Per Oral	B
Ceftizoxime		Parenteral	B
Ceftriaxone	Traxon®	Parenteral	B

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Cefuroxime	Sefur®	Per Oral	B
		Parenteral	B
Celecoxib	Citin®	Per Oral	C; D in 3 rd trim
		Per Oral	B; D in 2 nd & 3 rd trim
Celiprolol	Conicol®	Per Oral	B
		Per Oral	D
Cetirizine	Kevilon®	Ophthalmic	C
		Ear	C
Chlorambucil	Opsonil®	Parenteral	C
		Mouth/Throat	B
Chloramphenicol	Histal®	Periodontal implant	C
		Per Oral	C
Chlorhexidine	Cinaryl®	Ear	C
		Per Oral	B
Chloroquine	Ciprox®	Per Oral	C
		Parenteral	C
Chloroxylenol	Klabex®	Per Oral	C
		Per Oral	B
Chlorphenamine	Histal®	Parenteral	C
		Per Oral	B
Chlorpromazine	Cinaryl®	Per Oral	C
		Parenteral	B
Chlortalidone	Ciprox®	Per Oral	C
		Per Oral	B
Chlorpheniramine Maleate	Klabex®	Parenteral	C
		Per Oral	D
Cilastatin	Histal®	Per Oral	C
		Parenteral	C
Cilazapril	Cinaryl®	Per Oral	B
		Parenteral	B
Cilostazol	Ciprox®	Per Oral	C
		Per Oral	C
Cimetidine	Klabex®	Parenteral	B
		Per Oral	C
Cinnarizine	Ciprox®	Parenteral	B
		Per Oral	C
Ciprofloxacin	Klabex®	Ophthalmic	C
		Per Oral	C
Cisapride	Ciprox®	Ear	C
		Parenteral	C
Cisplatin	Klabex®	Per Oral	C
		Per Oral	D
Citalopram	Klabex®	Parenteral	C
		Per Oral	C
Clarithromycin	Klabex®	Per Oral	C

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Clavulanic Acid		Parenteral	C
Clindamycin	Clindax®	Per Oral	B
		Per Oral	B
		Parenteral	B
		Topical	B
		Vaginal	B
Clobetasol	Dermex®	Topical	C
Clomifene		Per Oral	X
Clomipramine		Per Oral	C
Clonazepam	Pase®	Per Oral	D
		Parenteral	D
		Epidural	C
Clonidine		Per Oral	C
		Parenteral	C
		Transdermal	C
Clopidogrel	Clont®	Per Oral	B
Clotrimazole	Trimazole®	Topical	B
Cloxacillin		Vaginal	B
Clozapine	Cloxin®	Per Oral	B
Codeine		Per Oral	C; D if prolonged use
Colchicine		Parenteral	C; D if prolonged use
Colecalciferol		Per Oral	D
Cortisone		Per Oral	C; D if dose > US RDA
Crotamiton		Per Oral	C; D in 1 st trim
Cyanocobalamin		Parenteral	C; D in 1 st trim
Cyclobenzaprine		Topical	C
Cyclopentolate		Nasal	C
Cyclophosphamide		Per Oral	B
Cyproheptadine		Ophthalmic	C
		Per Oral	D
		Parenteral	D
		Per Oral	B

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Danazol		Per Oral	X
Dapsone		Per Oral	C
Darifenacin		Per Oral	C
Deferoxamine		Parenteral	C
Desloratadine	Des®	Per Oral	C
Desogestrel		Per Oral	X
Desonide		Topical	C
Dexamethasone	Decason®	Ophthalmic	C
Dextran		Per Oral	C; D in 1 st trim
Dextromethorphan		Parenteral	C; D in 1 st trim
Diazepam	Easium®	Parenteral	C
Diclofenac	Diclofen®	Per Oral	C
Dicycloverine HCl	Abdorin®	Per Oral	D
Diflorasone		Parenteral	D
Digitoxin		Rectal	D
Digoxin	Centoxin®	Ophthalmic	C; D in 3 rd trim
Diltiazem		Per Oral	C; D in 3 rd trim
Dimenhydrinate		Parenteral	C; D in 3 rd trim
Dinoprostone		Topical	B
Diphenhydramine	Rymin®	Per Oral	B
Dipyridamole		Topical	C
Disopyramide		Per Oral	C
Dobutamine		Per Oral	C
Donepezil		Parenteral	B
Dopamine		Per Oral	C
		Parenteral	C

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Doxepin		Per Oral	C
Doxorubicin		Parenteral	D
Doxycycline	Doxin®	Per Oral	D
Duloxetine	Xinolax DR®	Per Oral	C
Dutasteride		Per Oral	X
Econazole	Ecozol®	Topical Vaginal	C; Avoid in 1 st trim C; Avoid in 1 st trim
Emedastine		Per Oral	B
Enalapril		Per Oral	C; D in 2 nd & 3 rd trim
Entacapone		Per Oral	C
Entecavir	Enviral®	Per Oral	C
Ephedrine		Parenteral Per Oral	C C
Epinastine		Ophthalmic	C
Epinephrine		Nasal Ophthalmic Parenteral	C C C
Eplerenone		Per Oral	B
Ergocalciferol		Per Oral Parenteral	A; D if dose > US RDA A; D if dose > US RDA
Ergometrine		Parenteral Buccal Per Oral Rectal	X X X X
Erythromycin	Ermac®	Per Oral	B
Escitalopram	Citalex®	Parenteral	B
Esomeprazole	Esotid®	Topical	B
Estradiol		Per Oral Mouth/Throat Per Oral Transdermal Vaginal	C B X X X

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Eszopiclone	Esleep®	Per Oral	C
Ethambutol		Per Oral	B
Ethosuximide		Per Oral	C
Etodolac	Edolac®	Per Oral	C; D in 3 rd trim
Ezetimibe		Per Oral	D
Famciclovir		Per Oral	B
Famotidine	Peptid®	Per Oral	B
Fenofibrate	Tigirate®	Per Oral	C
Fentanyl		Buccal	C; D if prolonged use
		Parenteral	C; D if prolonged use
		Transdermal	C; D if prolonged use
Fexofenadine	Fixal®	Per Oral	C
Filgrastim		Parenteral	C
Finasteride		Per Oral	X
Flavoxate	Avox®	Per Oral	B
Fluconazole	Flucon®	Per Oral	C
Fluorometholone		Parenteral	C
Fluorouracil		Ophthalmic	C
		Parenteral	X
Flupentixol		Topical	X
Fluphenazine		Parenteral	C
Flurazepam		Per Oral	C
Flurbiprofen		Parenteral	C
Fluticasone	Fluvate®	Per Oral	X
		Ophthalmic	B; D in 3 rd trim
		Per Oral	B; D in 3 rd trim
		Inhalation	C
Fluvastatin	Lesterol®	Nasal	C
Fluvoxamine		Topical	C
Formoterol		Per Oral	X
Furosemide	Frusin®	Per Oral	C
		Inhalation	C
		Per Oral	C

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Gabapentin	Gpentin®	Parenteral	C
Galantamine		Per Oral	C
Gatifloxacin	Tget®	Per Oral	B
Gemfibrozil		Ophthalmic	C
Gemifloxacin	Flogem®	Per Oral	C
Gentamicin	Gentin®	Parenteral	C
Glibenclamide	Glucon®	Per Oral	C
Gliclazide	Glizid®	Per Oral	C
Glimepiride	Glims®	Per Oral	C
Glipizide		Per Oral	C
Gliclazide	Glizid®	Per Oral	C
Glycerol		Topical	C
Griseofulvin		Per Oral	C
Guaifenesin		Per Oral	C
Guanethidine		Per Oral	C
Halcinonide		Topical	C
Haloperidol	Halop®	Per Oral	C
Heparin		Parenteral	C
Homatropine		Parenteral	C
Hydralazine		Ophthalmic	C
Hydrochlorothiazide		Per Oral	C
Hydrocortisone	Cotson®	Ophthalmic	C; D in 1 st trim
		Per Oral	C; D in 1 st trim
		Ear	C; D in 1 st trim
		Parenteral	C; D in 1 st trim

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Hydroquinone		Topical	C; D in 1 st trim
Hydroxocobalamin		Topical	C
Hydroxyzine		Parenteral	A; C if dose > US RDA
Hyoscine	Xyrid®	Per Oral	C
Ibandronic Acid	Hysomide®	Per Oral	C
Ibuprofen	Bonfix®	Per Oral	C
Idoxuridine	Advel®	Per Oral	B; D in 3 rd trim
Imipenem	Maxipen®	Ophthalmic	C
Imipramine		Parenteral	C
Indapamide		Per Oral	D
Indomethacin	Hypen SR®	Parenteral	D
Iodine	Indomet®	Per Oral	B
Iopamidol		Ophthalmic	B; D if used for >48 hr
Irbesartan		Per Oral	B; D if used for >48 hr
Isoniazid		Parenteral	B; D if used for >48 h
Kanamycin		Rectal	B; D if used for >48 hr
Kaolin	Arbitan®	Per Oral	D
Ketamine		Parenteral	B
Ketoconazole	Ketocon®	Per Oral	C
Ketoprofen		Topical	C
Ketorolac tromethamine	Todol®	Per Oral	B; D in 3 rd trimester
Ketotifen	Kofen®	Ophthalmic	C
Labetalol		Ophthalmic	C
		Per Oral	C; D in 2 nd & 3 rd trim
		Parenteral	C; D in 2 nd & 3 rd trim

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Lactulose	Laclose®	Per Oral	B
Lamivudine		Per Oral	C
Lamotrigine		Per Oral	C
Lansoprazole	Lantid®	Per Oral	B
Latanoprost		Ophthalmic	C
Leflunomide		Per Oral	X
Letrozole		Per Oral	D
Levamisole	Vermicom®	Per Oral	C
Levamisole	Vermicom®	Per Oral	C
Levetiracetam		Per Oral	C
Levobunolol		Ophthalmic	C
Levobupivacaine		Parenteral	B
Levocetirizine		Per Oral	B
Levodopa		Per Oral	C
Levofloxacin	Levox®	Ophthalmic	C; contr in 1 st trim
		Per Oral	C; contr in 1 st trim
		Parenteral	C; contr in 1 st trim
Levonorgestrel		Per Oral	X
		Subdermal	X
Lidocaine		Parenteral	B; as cardiac drug
		Topical	B
Linezolid	Linexil®	Per Oral	C
		Parenteral	C
Lisinopril		Per Oral	C; D in 2 nd & 3 rd trim
Lithium		Per Oral	D
Lodoxamide		Ophthalmic	B
Lomefloxacin	Lomexa®	Ophthalmic	C
Loperamide	Loperin®	Per Oral	B
Loratadine	Lora®	Per Oral	B
Lorazepam		Per Oral	D
Losartan Potassium	Larb®	Parenteral	D
		Per Oral	C; D in 2 nd & 3 rd trim
Lovastatin		Per Oral	X

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Lynestrenol		Per Oral	D
Magaldrate		Per Oral	C
Magnesium hydroxide	MOM®	Per Oral	B
Mannitol		Parenteral	C
Maprotiline		Per Oral	B
Mebendazole	Solas®	Per Oral	C
Meclizine	Emego®	Per Oral	B
Mefenamic acid	Amifen®	Per Oral	C; D in 3 rd trim
Mefloquine		Per Oral	C
Meloxicam		Per Oral	C; D in 3 rd trim term
Melphalan		Per Oral	D
Memantine		Parenteral	D
Mepyramine		Per Oral	B
Mercaptopurine		Per Oral	C
Meropenem	Ronem®	Parenteral	D
Mesalazine		Per Oral	B
Metformin	Met®	Rectal	B
Methotrexate		Per Oral	B
Methoxsalen		Per Oral	X
Methyldopa	Dopamet®	Parenteral	X
Methylprednisolone		Per Oral	C
Metolazone		Topical	C
Metoclopramide	Metocol®	Per Oral	B
Metoprolol	Preloc®	Per Oral	C; D in 2 nd & 3 rd trim
Metronidazole	Metyl®	Per Oral	B
		Parenteral	B

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Miconazole	Unigal®	Topical	B
		Topical	C
		Vaginal	C
Midazolam	Midolam®	Per Oral	D
		Parenteral	D
Minoxidil	Nasonex®	Per Oral	C
Mirtazapine		Per Oral	C
Misoprostol		Per Oral	X
Mometasone furoate	Trilock®	Nasal	C
Montelukast		Topical	C
Morphine		Per Oral	B
Moxifloxacin	Moxilocin®	Per Oral	C
		Parenteral	C
		Ophthalmic	C
		Per Oral	C
Mupirocin	Dermoban®	Parenteral	C
		Topical	B
		Ophthalmic	B
Nalbuphine	Raltrox®	Topical	B
		Parenteral	B; D if prolonged use
		Parenteral	X
Nandrolone	Naxin®		C
Naphazoline		Per Oral	B; D in 3 rd trim
Naproxen		Ophthalmic	C
Natamycin	Neocin®	Per Oral	C
Nateglinide		Inhalation	B
Nedocromil		Ophthalmic	B
Nelfinavir	Neocin®	Per Oral	B
Neomycin		Topical	C
Neostigmine		Per Oral	C
Netilmicin	Neocin®	Parenteral	C
Nevirapine		Per Oral	D
			C

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Nifedipine		Per Oral	C
Nimodipine		Per Oral	C
Nitazoxanide	Zoxan®	Parenteral	C
Nitrofurantoin	Urobak®	Per Oral	B
Norethisterone		Per Oral	B
Norfloxacin		Ophthalmic	X
Norgestrel		Per Oral	C
Nortriptyline		Per Oral	C
		Per Oral	X
		Per Oral	D
		Mouth/throat	C
Nystatin	Naf®	Per Oral	C
		Topical	C
		Vaginal	A
		Ophthalmic	C; Caution 1 st trim
Ofloxacin	Flocet®	Per Oral	C; Caution 1 st trim
		Ear	C; Caution 1 st trim
		Parenteral	C; Caution 1 st trim
Olanzapine		Per Oral	C
Olmesartan medoxomil	Olsart®	Per Oral	C; D in 2 nd & 3 rd trim
Olopatadine	Opatin®	Ophthalmic	C
Omeprazole	Ometid®	Per Oral	C
		Parenteral	C
Ondansetron	Anset®	Per Oral	B
		Parenteral	B
Orlistat		Per Oral	B
Oseltamivir		Per Oral	C
Oxaprozin		Per Oral	C; D in 3 rd trim
Oxazepam		Per Oral	D
Oxcarbazepine		Per Oral	C
Oxiconazole		Topical	B
Oxybuprocaine		Ophthalmic	C

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Oxybutynin		Per Oral	B
Oxymetazoline	Oxynex	Nasal	C
Oxyphenonium bromide	Antrenex®	Ophthalmic	C
Oxytetracycline		Per Oral	C
Oxytocin	Ocin®	Per Oral	D
Paclitaxel		Pareteral	X
Palonosetron	Panoset®	Parenteral	D
Pancreatin	Crezyme®	Per Oral	B
Pantoprazole	Pantid®	Parenteral	B
Paracetamol	Renova®	Per Oral	B
Paroxetine		Per Oral	D
Paracetamol	Renova®	Per Oral	B
Pentazocine		Per Oral	C; D if prolonged use
Pentoxifylline		Parenteral	C; D if prolonged use
Perindopril		Rectal	C; D if prolonged use
Permethrin	Lorix®	Per Oral	C
		Per Oral	C; D in 2 nd & 3 rd trim
Pethidine		Topical	B
Pheniramine	Amarin®	Per Oral	B; D if prolonged use
Phenoxyme thylpenicillin	Open®	Parenteral	B; D if prolonged use
Phenylephrine		Per Oral	C
Phenytoin		Per Oral	D
Phytomenadione		Parenteral	D
Pilocarpine	Piloma®	Per Oral	C
		Parenteral	C
		Ophthalmic	C

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Pimecrolimus		Per Oral	C
Pioglitazone		Topical	C
Piperacillin	Piol®	Per Oral	C
Piroxicam		Parenteral	B
Povidone-iodine		Per Oral	C; D in 3 rd trim
Pramipexole	Povin®	Topical	D
Prazosin		Per Oral	C
Prednisolone		Per Oral	C
Prednisone	Precodil®	Ophthalmic	C
Pregabalin		Per Oral	C; D in 1 st trim
Primaquine		Parenteral	C; D in 1 st trim
Procaine		Per Oral	C; D in 1 st trim
Prochlorperazine	Pregaba®	Per Oral	C
Procyclidine		Parenteral	C
Promazine		Rectal	C
Promethazine	Vergon®	Per Oral	C
Propofol		Parenteral	C
Propranolol HCl	Propranolol®	Per Oral	C; D in 2 nd & 3 rd trim
Pseudoephedrine		Per Oral	C
Pyrantel		Per Oral	C
Pyrazinamide		Per Oral	C
Pyridoxine		Per Oral	A
Pyrimethamine		Parenteral	A
Quetiapine		Per Oral	C
Quinine		Per Oral	X
		Parenteral	X

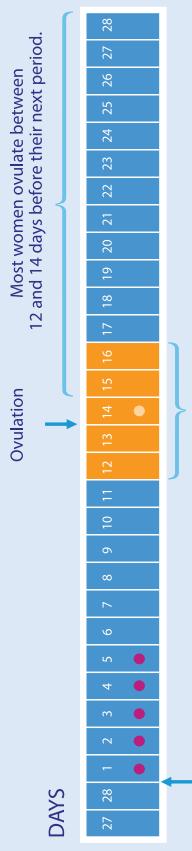
Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Rabeprazole	Finix®	Per Oral	B
Raloxifene		Per Oral	X
Ramipril	Ramace®	Per Oral	C; D in 2 nd & 3 rd trim
Ranitidine	Ranitid®	Per Oral	B
Repaglinide	Repanid®	Parenteral	B
		Per Oral	C
Ribavirin		Inhalation	X
		Per Oral	X
		Parenteral	X
Riboflavin		Per Oral	A; C if dose>US RDA
Rifampicin		Per Oral	C
		Parenteral	C
Risperidone	Risperdex®	Per Oral	C
Rivastigmine		Per Oral	B
Rizatriptan		Per Oral	C
Rofecoxib		Per Oral	C; D in 3 rd trim
Ropinirole		Per Oral	C
Rosiglitazone		Per Oral	C
Rosuvastatin	Ropitor®	Per Oral	X
Rupatadine	Rufast®	Per Oral	C
		Inhalation	C
Salbutamol	Pulmolin®	Per Oral	C
		Parenteral	C
Salmeterol		Inhalation	C
Scopolamine		Transdermal	C
Selegiline		Per Oral	C
Sennosides A & B		Per Oral	C
Sertraline	Mudiral®	Per Oral	C
Sibutramine		Per Oral	C
Simethicone	Flatulex®	Per Oral	C
Sildenafil	Viax®	Per Oral	B
Silver Sulphadiazine	Neozinc®	Per Oral	C
Simvastatin		Per Oral	X

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Sotalol		Per Oral	B; D in 2 nd & 3 rd trim
Sparfloxacin		Parenteral	B; D in 2 nd & 3 rd trim
Spectinomycin		Per Oral	C
Streptokinase		Per Oral	C
Streptomycin		Parenteral	C
Sucralfate		Parenteral	D
Sulfacetamide		Per Oral	B
Sulfacetamide		Ophthalmic	C
Sulfadiazine		Topical	C
Sulfamethizole		Per Oral	C;
Sulfamethoxazole		Per Oral	C;
Sulfasalazine	Salazine®	Per Oral	B;
Sulindac	Clinorel®	Rectal	B;
Sumatriptan		Per Oral	C
Tacrolimus		Nasal	C
Tadalafil		Per Oral	C
Tamoxifen		Parenteral	C
Tamsulosin	Tealis®	Topical	C
Tazarotene		Per Oral	B
Tegaserod		Per Oral	D
Telmisartan	Urinom®	Per Oral	B
Terazosin		Topical	X
Terbinafine		Per Oral	B
		Per Oral	B
		Per Oral	C
		Per Oral	B
		Topical	B
		Inhalation	B
		Per Oral	B
		Parenteral	B

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Terfenadine		Per Oral	C
Testosterone		Per Oral	X
		Parenteral	X
		Topical	X
		Transdermal	X
Tetracycline		Ophthalmic	D
		Per Oral	D
		Topical	B
Theophylline	Unilin®	Per Oral	C
Thiamine		Parenteral	C
Thioridazine		Per Oral	A; C if dose > US RDA
Ticlopidine		Per Oral	C
Timolol		Per Oral	B
Tioconazole		Ophthalmic	C
Tizanidine		Per Oral	C; D in 2 nd & 3 rd trim
Tobramycin	Ticoma®	Vaginal	C
Topiramate	Tizalud®	Per Oral	C
Torsemide	Torcin®	Inhalation	D
Tramadol		Ophthalmic	B
		Parenteral	D
		Per Oral	C
		Per Oral	B
		Parenteral	B
Tranexamic acid	Tranal®	Per Oral	C
Travoprost	Enclot®	Parenteral	C
Tretinoin		Per Oral	B
		Parenteral	B
Triamcinolone		Ophthalmic	C
		Per Oral	D
		Topical	C
		Inhalation	C
		Nasal	C
		Per Oral	C; D in 1 st trim

Generic Name ^{7,8}	Opsonin Brands	Route Of Administration (ROA)	Pregnancy Category US FDA
Triamterene		Parenteral	D; D in 1 st trim
Trifluoperazine		Topical	C
Trimethoprim		Per Oral	C
Tripolidine		Per Oral	C
Tropicamide		Per Oral	C
Urea		Ophthalmic	C
Ursoodeoxycholic acid	Liconor®	Topical	C
Valaciclovir		Per Oral	B
Valdecoxib		Per Oral	B
Valsartan		Per Oral	C
Vancomycin	Vancomin®	Per Oral	C; D in 2 nd & 3 rd trim
Verapamil		Parenteral	B
Vinblastine		Per Oral	C
Vincristine		Parenteral	C
Vitamin E	Ovit-E®	Parenteral	D
Warfarin		Per Oral	D
Xylometazoline HCl	Xylomet®	Per Oral	A; C if dose > US RDA
Zidovudine		Per Oral	X
Ziprasidone		Nasal	C
Zolmitriptan		Per Oral	C
Zolpidem		Parenteral	C
Zuclopentixol		Per Oral	C
		Per Oral	B
		Parenteral	C

This chart shows a 28-day cycle. It may be longer or shorter.



Pregnancy Due Date calendar

■ The date of conceived
■ The estimated delivery date

Jan	Oct	Feb	Nov	Mar	Dec	Apr	Jan	May	Feb	Jun	Mar	Jul	Aug	May	Sep	Jun	Oct	Jul	Nov	Aug	Dec	Sep
1	8	1	8	1	6	1	6	1	5	1	8	1	7	1	8	1	8	1	8	1	7	
2	9	2	9	2	7	2	6	2	6	2	9	2	8	2	9	2	9	2	9	2	8	
3	10	3	10	3	8	3	8	3	7	3	10	3	9	3	10	3	10	3	10	3	9	
4	11	4	11	4	9	4	9	4	8	4	11	4	10	4	11	4	11	4	11	4	10	
5	12	5	12	5	10	5	10	5	9	5	12	5	11	5	12	5	12	5	12	5	11	
6	13	6	13	6	11	6	11	6	10	6	13	6	12	6	13	6	13	6	13	6	12	
7	14	7	14	7	12	7	12	7	11	7	14	7	13	7	14	7	14	7	14	7	13	
8	15	8	15	8	13	8	13	8	12	8	15	8	14	8	15	8	15	8	15	8	14	
9	16	9	16	9	14	9	14	9	13	9	16	9	15	9	16	9	16	9	16	9	15	
10	17	10	17	10	15	10	15	10	14	10	17	10	16	10	17	10	17	10	17	10	16	
11	18	11	18	11	16	11	16	11	15	11	18	11	17	11	18	11	18	11	18	11	17	
12	19	12	19	12	17	12	17	12	16	12	19	12	18	12	19	12	19	12	19	12	18	
13	20	13	20	13	19	13	19	13	17	13	20	13	19	13	20	13	20	13	20	13	19	
14	21	14	21	14	19	14	19	14	18	14	21	14	20	14	21	14	21	14	21	14	20	
15	22	15	22	15	20	15	20	15	19	15	22	15	21	15	22	15	22	15	22	15	21	
16	23	16	23	16	21	16	21	16	20	16	23	16	22	16	23	16	23	16	23	16	22	
17	24	17	24	17	22	17	22	17	21	17	24	17	23	17	24	17	24	17	24	17	23	
18	25	18	25	18	23	18	23	18	22	18	25	18	24	18	25	18	25	18	25	18	24	
19	26	19	26	19	24	19	24	19	23	19	26	19	25	19	26	19	26	19	26	19	25	
20	27	20	27	20	25	20	25	20	24	20	27	20	26	20	27	20	27	20	27	20	26	
21	28	21	28	21	26	21	26	21	25	21	28	21	27	21	28	21	28	21	28	21	27	
22	29	22	29	22	27	22	27	22	26	22	29	22	28	22	29	22	29	22	29	22	28	
23	30	23	30	23	28	23	28	23	27	23	30	23	29	23	30	23	30	23	30	23	29	
24	31	24	31	24	29	24	29	24	28	24	31	24	30	24	31	24	31	24	31	24	30	
25	1	25	2	25	30	25	30	25	1	25	1	25	1	25	1	25	1	25	1	25	1	
26	2	26	3	26	31	26	31	26	2	26	2	26	2	26	2	26	2	26	2	26	2	
27	3	27	4	27	1	27	1	27	3	27	3	27	3	27	3	27	3	27	3	27	3	
28	4	28	5	28	2	28	2	28	4	28	4	28	4	28	4	28	4	28	4	28	4	
29	5	29	6	29	3	29	3	29	5	29	5	29	5	29	5	29	5	29	5	29	5	
30	6	30	7	30	4	30	4	30	6	30	6	30	6	30	6	30	6	30	6	30	6	
31	7	31	8	31	7	31	7	31	7	31	7	31	7	31	7	31	7	31	7	31	7	



References:

1. http://en.wikipedia.org/wiki/Pregnancy_category
2. <http://www.netdoctor.co.uk/>
3. Food and Drug Administration. Federal Register 1980; 44:37434-67
4. www.tga.gov.au
5. www.dh.gov.uk
6. www.drugs.com
7. IMS, 2nd Quarter' 2012
8. www.pharmacy.cmu.ac.th/dic/guideline/pregnancy_index.htm

This is circulated with the prior approval of Licensing Authority (Drugs).
Madona / OPH-L-201411-52 | Pregnancy Safety Index 1st Print-2015

FURTHER INFORMATION IS AVAILABLE FROM:
Opsonin Pharma Limited

Product Management Department, Opsonin Building
30 New Eskaton, Dhaka 1000, Visit our website: www.opsonin.com

