

Australian categorisation system for prescribing medicines in pregnancy

Pregnancy Category A Drugs which 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 foetus having been observed.

Pregnancy Category B1 Drugs which 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 foetus having been observed.
Studies in animals have not shown evidence of an increased occurrence of fetal damage.

Pregnancy Category B2 Drugs which 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 foetus having been observed.
Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of foetal damage.

Pregnancy Category B3 Drugs which 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 foetus having been observed.
Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans.

Pregnancy Category C Drugs which, owing to their pharmaceutical effects, have caused or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformations. These effects may be reversible.

Pregnancy Category D Drugs which have caused, are suspected to have caused or may be expected to cause, an increased incidence of human foetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects.

Examples: Angiotensin converting enzyme (ACE) inhibitors (captopril, cilazapril,

enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, trandolapril), Angiotensin II receptor antagonists (ARAs) (candesartan cilexetil, eprosartan, irbesartan, losartan, valsartan), Anticonvulsants / Antiepileptics (carbamazepine, phenytoin sodium, methylphenobarbitone, phenobarbitone, primidone, sodium valproate (valproic acid), lamotrigine, ethosuximide, methsuximide, phensuximide, sulthiame, vigabatrin), Antirheumatoid agents (hydroxychloroquine), Muscle relaxants (quinine), Endocrine system (estrogens conjugated, Dydrogesterone, hydroxyprogesterone, megestrol, norethisterone, Fluoxymesterone, methenolone, nandrolone, oxandrolone, oxymetholone, testosterone, Nafarelin, goserelin, Aminoglutethimide, Danazol, Gestrinone), Antimicrobials (Tetracyclines Demeclocycline, doxycycline, minocycline, tetracycline)

Pregnancy Category X Drugs which have such a high risk of causing permanent damage to the foetus that they should not be used in pregnancy or when there is a possibility of pregnancy.

Examples: Misoprostol, Dienoestrol, Raloxifene, Finasteride, Ribavirin, Tretinoin (Oral), Isotretinoin, sodium phosphate P³²