
10. Appendix

Categorisation of risk of drug use in pregnancy

(From 'Medicines in Pregnancy' 2nd Edition. Australian Drug Evaluation Committee: Canberra, 1992)

Category A: Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Category B: 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 malformations or other direct or indirect harmful effects on the human fetus having been observed.

As experience of effects of drugs in this category in humans is limited, results of toxicological studies to date (including reproduction studies in animals) are indicated by allocation of one of three subgroups:

Group B1: Studies in animals have not shown evidence of an increased occurrence of fetal damage.

Group B2: Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.

Group B3: Studies in animals have shown evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.

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

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

