

Category of Drugs

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Categories of drugs

The following information is taken from the Therapeutic Goods Administration. Prescribing medicines in pregnancy 4th edition. 2000.

Australian categorisation consists of the following categories:

Category A / Category B1 / Category B2 / Category B3 / Category C / Category D / Category X

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 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 fetus having been observed.

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

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 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.

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 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.

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. Accompanying texts should be consulted for further details.

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. Accompanying texts should be consulted for further details.

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South Australian Paediatric Clinical Guidelines Reference Committee. South Australian Child Health Clinical Network

South Australian Paediatric Clinical Guidelines Reference Committee:
cywhs.paediatricclinicalguidelines@health.sa.gov.au

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Category X

Drugs which 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.

Note: For drugs in the B1, B2 and B3 categories, human data are lacking or inadequate and subcategorisation is therefore based on available animal data. The allocation of a B category does NOT imply greater safety than the C category. Drugs in category D are not absolutely contraindicated in pregnancy (e.g. anticonvulsants). Moreover, in some cases the 'D' category has been assigned on the basis of 'suspicion'.

Due to legal considerations in this country, sponsor companies have, in some cases, applied a more restrictive category than can be justified on the basis of the available data.

In some cases there may be discrepancies between the published Product Information and the information in this booklet due to the process of ongoing document revision.

Reference

1. Therapeutic Goods Administration (TGA). Prescribing medicines in pregnancy 4th edition [online] 2000 February [cited 2004 Feb 2]. Available from: URL: <http://www.tga.gov.au/docs/html/mip/intro.htm>

Version control and change history

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1.0	2013	Current	Original version

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