# 附錄二 孕婦用藥安全評估

根據**FDA**標準, 分為五級, 以便處方及調劑藥品者可以快速了解藥品對懷孕婦女及胎兒的安全

**Risk Factors**

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| **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 trimesters), and the possibility of fetal harm appears remote. |
| **Category B:** | Animal reproduction studies have not demonstrated a fetal risk, but there are no controlled studies in pregnant women. Alternatively, 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). |
| **Category C:** | 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. |
| **CategoryD:** | 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). |
| **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 drug in pregnant women clearly outweighs in women who are or may become pregnant. |

DEFINITIONS OF PREGNANCY RECOMMENDATIONS

form *Drugs in pregnancy and lactation: A reference guide to fetal and neonatal risk, 11th edition*.

**COMPATIBLE**

The human pregnancy experience, either for the drug itself or drugs in the same class or with similar mechanisms of action, is adequate to demonstrate that the embryo–fetal risk is very low or nonexistent. Animal reproduction data are not relevant.

**NO (LIMITED) HUMAN DATA—PROBABLY COMPATIBLE**

There may or may not be human pregnancy experience, but the characteristics of the drug suggest that it does not represent a significant risk to the embryo–fetus. For example, other drugs in the same class or with similar mechanisms are compatible or the drug does not obtain significant systemic concentrations. Any animal reproduction data are not relevant.

**COMPATIBLE—MATERNAL BENEFIT >> EMBRYO–FETAL RISK**

There may or may not be human pregnancy experience, but the potential maternal benefit far outweighs the known or unknown embryo–fetal risk. Animal reproduction data are not relevant.

**HUMAN DATA SUGGEST LOW RISK**

There is limited human pregnancy experience, either for the drug itself or drugs in the same class or with similar mechanisms of action, including the 1st trimester, suggesting that the drug does not represent a significant risk of developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death) at any time in pregnancy. The limited human pregnancy data outweighs any animal reproduction data.

**NO (LIMITED) HUMAN DATA—ANIMAL DATA SUGGEST LOW RISK**

Either there is no human pregnancy experience or the few pregnancy exposures have not been associated with developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death). The drug does not cause developmental toxicity (at doses that did not cause maternal toxicity) in all animal species studied at doses ≤10 times the human dose based on body surface area (BSA) or AUC\*.

**NO (LIMITED) HUMAN DATA—ANIMAL DATA SUGGEST MODERATE RISK**

Either there is no human pregnancy experience or the few pregnancy exposures have not been associated with developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death). The drug causes developmental toxicity (at doses that did not cause maternal toxicity) in one animal species at doses ≤10 times the human dose based on body surface area (BSA) or AUC\*.

**NO (LIMITED) HUMAN DATA—ANIMAL DATA SUGGEST RISK**

Either there is no human pregnancy experience or the few pregnancy exposures have not been associated with developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death). The drug causes developmental toxicity (at doses that did not cause maternal toxicity) in two animal species at doses ≤10 times the human dose based on body surface area (BSA) or AUC\*.

**NO (LIMITED) HUMAN DATA—ANIMAL DATA SUGGEST HIGH RISK**

Either there is no human pregnancy experience or the few pregnancy exposures have not been associated with developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death). The drug causes developmental toxicity (at doses that did not cause maternal toxicity) in three or more animal species at doses ≤10 times the human dose based on body surface area (BSA) or AUC\*.

**CONTRAINDICATED—1ST TRIMESTER**

Human exposures in the 1st trimester, either to the drug itself or to drugs in the same class or with similar mechanisms of action, have been associated with developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death). The drug should not be used in the 1st trimester.

**CONTRAINDICATED—2ND AND 3RD TRIMESTERS**

Human exposures in the 2nd and 3rd trimesters, either to the drug itself or to drugs in the same class or with similar mechanisms of action, have been associated with developmental toxicity (growth restriction, structural anomalies, functional/behavior deficits, or death). The drug should not be used in the 2nd and 3rd trimesters.

**CONTRAINDICATED**

Human exposures at any time in pregnancy, either to the drug itself or to drugs in the same class or with similar mechanisms of action, have been associated with developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death). Animal reproduction data, if available, confirm the risk. The drug should not be used in pregnancy.

**NO (LIMITED) HUMAN DATA—NO RELEVANT ANIMAL DATA**

There are no human pregnancy data or relevant data in animals, or the human pregnancy experience, that may or may not include the 1st trimester, is limited. The risk in pregnancy cannot be assessed.

**HUMAN DATA SUGGEST RISK IN 1ST TRIMESTER**

Evidence (for the drug or similar drugs) suggests that there may be an embryo–fetal risk for developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death) in the 1st trimester but not in the 2nd and 3rd trimesters. The human pregnancy data outweigh any animal reproduction data.

**HUMAN DATA SUGGEST RISK IN 1ST AND 3RD TRIMESTERS**

Evidence (for the drug or similar drugs) suggests that there may be an embryo–fetal risk for developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death) in the 1st and 3rd trimesters but not in the 2nd trimester. The human pregnancy data outweigh any animal reproduction data.

**HUMAN DATA SUGGEST RISK IN 2ND AND 3RD TRIMESTERS**

Evidence (for the drug or similar drugs) suggests that there may be a fetal risk for developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death) in the 2nd and 3rd trimesters but not in the 1st trimester. The human pregnancy data outweigh any animal reproduction data.

**HUMAN DATA SUGGEST RISK IN 3RD TRIMESTER**

Evidence (for the drug or similar drugs) suggests that there may be a fetal risk for developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death) in the 3rd trimester, or close to delivery but not in the 1st or 2nd trimesters. The human pregnancy data outweigh any animal reproduction data.

**HUMAN (AND ANIMAL) DATA SUGGEST RISK**

The human data for the drug or drugs in the same class or with the same mechanism of action, and animal reproduction data if available, suggest that there may be a risk for developmental toxicity (growth restriction, structural anomalies, functional/behavioral deficits, or death) throughout pregnancy. Usually, pregnancy exposure should be avoided, but the risk may be acceptable if the maternal condition requires the drug.

資料來源: Briggs, G. G. (2017). *Drugs in pregnancy and lactation: A reference guide to fetal and neonatal risk*. Wolters Kluwer.