# 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. |