

衛生署藥物辦公室
藥物資訊及警戒科

香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室



DEPARTMENT OF HEALTH
DRUG OFFICE

DRUG INFORMATION AND
PHARMACOVIGILANCE DIVISION

Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

電話號碼 Tel. No.: 3974 4175

詢問處 Enquiries: (852) 3974 4175

傳真號碼 Faxline No.: (852) 2803 4962

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Dear Healthcare Professionals,

Updated contraception advice for tamoxifen

Your attention is drawn to the Therapeutic Goods Administration's (TGA) announcement that the recommended duration of contraception after finishing tamoxifen treatment has been extended from two months to nine months. This means women should continue their contraception and not become pregnant for at least nine months after tamoxifen therapy has ended.

Tamoxifen is contraindicated in pregnancy and the possibility of pregnancy should be excluded before treatment is started. Women of child-bearing potential should be advised to use barrier or other non-hormonal contraceptive methods if they are sexually active, both during treatment and for nine months after treatment has ended. Women should be informed about the potential risks to the foetus, should they become pregnant while taking tamoxifen or within nine months of finishing treatment.

The Australian pregnancy category for tamoxifen remains unchanged - Category B3. A small number of reports of spontaneous abortions, birth defects and foetal deaths have occurred after women have taken tamoxifen, although no causal relationship has been established.

This change is based on the United States Food and Drug Administration guidance for genotoxic pharmaceuticals which recommends a minimum contraception period of six months plus five elimination half-lives after cessation of therapy.

Please refer to the following website in TGA for details:

<https://www.tga.gov.au/publication-issue/updated-contraception-advice-tamoxifen>

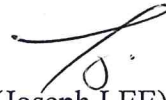
In Hong Kong, there are 13 registered pharmaceutical products containing tamoxifen, and all

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products are prescription-only medicines. So far, the Department of Health (DH) has received 10 cases of adverse drug reaction related to tamoxifen, but these cases are not related to abortions, birth defects and foetal deaths. In light of the above TGA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Joseph LEE)

for Assistant Director (Drug)