衞生署藥物辦公室
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
本署檔號 OUR REF.:

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

16 Sep 2021

Dear Healthcare Professionals,

Propylthiouracil and carbimazole: use in pregnancy

Your attention is drawn to the Therapeutic Goods Administration's (TGA) announcement that the pregnancy category for both propylthiouracil and carbimazole is being changed from category C to category D. A TGA safety assessment found that the Product Information (PI) documents for these medicines adequately described known risks relating to congenital abnormalities in neonates and therefore no changes or additions were required. However, it was determined that category D was the appropriate category for these products.

Reviewing a safety signal relating to congenital abnormalities for propylthiouracil and carbimazole, the TGA found that the current Australian PI documents for both medicines contained sufficient safety information under 'Section 4.6 Fertility, Pregnancy and Lactation'. Additionally, the carbimazole PI contains additional information on women of childbearing potential and pregnancy in 'Section 4.4 Special Warnings and Precautions for Use'.

However, the products were previously categorised under pregnancy category C, which is defined as 'Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformations. These effects may be reversible.'

As cases of congenital abnormalities have been reported in the post-market setting following use of these medicines, this category is no longer considered the correct pregnancy categorisation.

Category D is defined as 'Drugs which have caused, are suspected to have caused or may be expected to cause, an increased incidence of human foetal malformations or irreversible damage' and reflects the post-market experience with these medicines.

Propylthiouracil and carbimazole should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

Please refer to the following website in TGA for details:
https://www.tga.gov.au/publication-issue/propylthiouracil-and-carbimazole-use-pregnancy

In Hong Kong, there are registered pharmaceutical products containing propylthiouracil (5 products) and carbimazole (6 products). All products are prescription-only medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to propylthiouracil. The DH has received one case of adverse drug reaction related to carbimazole, but this case is not related to congenital abnormalities.

Related news on the risk of congenital malformations associated with the use of carbimazole during pregnancy was previously issued by the United Kingdom Medicines and Healthcare products Regulatory Agency and Singapore Health Sciences Authority, and was posted on the Drug Office website on 19 Feb 2019, 7 Mar 2019 and 12 Sep 2019. Currently, the sales pack or package insert of locally registered carbimazole-containing products should include safety information relevant to the risk of congenital malformations. Related news on the risk of birth defects associated with the use of propylthiouracil during pregnancy was previously issued by Health Canada, and was posted on the Drug Office website on 6 Apr 2020. 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,

(Ling PANG)
for Assistant Director (Drug)