

衛生署藥物辦公室  
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衛生檢測中心三樓



DEPARTMENT OF HEALTH  
DRUG OFFICE  
DRUG REGISTRATION AND  
IMPORT/EXPORT CONTROL DIVISION  
3/F., Public Health Laboratory Centre,  
382 Nam Cheong Street, Kowloon, Hong Kong

電話號碼 Tel. No.: 2319 8458

詢問處 Enquiries (852) 2319 8458

傳真號碼 Faxline No. (852) 2803 4962

本署檔號 OUR REF.: DH DO PRIE/7-30/15

16 February 2015

(來函請敘明此檔案號碼)

(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

**New Measures to Minimise Known Heart Risks of Hydroxyzine-containing Medicines**

The European Medicines Agency (EMA)'s Pharmacovigilance Risk Assessment Committee (PRAC) has completed a review of medicines containing the antihistamine hydroxyzine. This follows concerns over the risk of possible effects on heart rhythm with these medicines, which are available in most EU countries. Their approved uses (indications) vary considerably between countries and may include use to treat anxiety disorders, for relief of pruritus (itching), as premedication before surgery, and for treatment of sleep disorders.

The PRAC considered that hydroxyzine was associated with a small but definite risk of QT interval prolongation and torsade de pointes (alterations in the electrical activity of the heart that can lead to abnormal heart rhythms and cardiac arrest). Based on the assessed data, the risk did not differ between indications, and the Committee recommended that hydroxyzine could continue to be used provided that measures to minimise the risk of problems with heart rhythm were taken.

These measures include using the medicine at the lowest effective dose for as short a time as possible. Use is not recommended in the elderly. The maximum daily dose should be no more than 100 mg in adults (50 mg in the elderly if use cannot be avoided), and 2 mg per kg body weight where used in children up to 40 kg in weight. Use must be avoided in patients who already have risk factors for heart rhythm disturbances or are taking other medicines that increase the risk of QT prolongation. Care is also needed in patients taking medicines that slow the heart rate or decrease the level of potassium in the blood, as these also increase the risk of problems with heart rhythm.

The PRAC recommendation follows a detailed review of the available evidence, which included published studies and data from regular safety monitoring, as well as consultation with experts in the treatment of children and the elderly. PRAC confirmed the known possibility of QT interval prolongation and torsade de pointes with hydroxyzine, and noted that such events were most likely to occur in patients who had risk factors. The risk can therefore be decreased by restricting hydroxyzine use in those most at risk of heart rhythm problems and reducing exposure to the medicine. The Committee recommended further study and monitoring to ensure that these measures were effective. The product information should be updated accordingly.

The PRAC recommendation will now be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position and provide guidance to patients and healthcare professionals. In the interim, patients who have any concerns should consult their doctor or pharmacist.


Please refer to EMA's website for details:

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2015/02/news\\_detail\\_002265.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/02/news_detail_002265.jsp&mid=WC0b01ac058004d5c1)

In Hong Kong, there are 16 registered pharmaceutical products containing hydroxyzine and they are all prescription-only medicines. So far, the Department of Health (DH) has not received any relevant adverse reaction report related to hydroxyzine. In view of the findings by EMA, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. DH will remain vigilant, and will update the development related to hydroxyzine products to inform local healthcare professionals.

Please report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 or email: [adr@dh.gov.hk](mailto: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,

  
(Grant NG)  
for Assistant Director (Drug)