衞生署藥物辦公室
藥物註冊及進出口管制部

香港九龍南昌街 382 號公共衞生檢測中心三樓

2319 8458

電話號碼 Tel. No.:
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

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

10 July 2017

(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Injectable methylprednisolone products containing lactose must not be given to patients allergic to cow's milk proteins

Your attention is drawn to the European Medicines Agency's (EMA) announcement that the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended injectable methylprednisolone medicines containing lactose, which potentially contain traces of cow's milk proteins, must not be used in patients with a known or suspected allergy to the proteins in cow's milk. In addition, patients being treated for an allergic reaction with methylprednisolone should have their treatment stopped if their symptoms worsen or they develop new symptoms.

These recommendations follow a review which found that lactose derived from cow's milk may introduce traces of cow's milk proteins into the medicine which can trigger reactions in patients allergic to these proteins. This is of particular concern in patients already being treated for an allergic reaction as they are more prone to developing new allergic reactions. In this case it may be difficult to determine whether the patient's symptoms are due to a new allergic reaction caused by methylprednisolone products containing lactose or due to a worsening of the original condition. This may lead to additional doses being given which will further worsen the patient's condition.

Allergy to cow's milk proteins affects a small percentage of the population (up to 3 people in 100) and should not be confused with lactose intolerance which is a separate condition.

The PRAC concluded that there is no level of cow milk proteins that can be considered safe for these medicines when used to treat severe allergic reactions. Considering that methylprednisolone is used for the treatment of severe allergic reactions in an emergency setting where details of the patients' known allergies may not always be known, the PRAC recommended that the most effective way of minimising any risks is to remove cow's milk proteins from the preparation. The Committee therefore asked companies to take steps by middle of 2019 to replace current formulations containing cow's milk proteins with formulations that do not contain these proteins. In the meantime, the product information will be revised to reflect that injectable methylprednisolone products containing lactose must not be given to patients allergic to cow's milk proteins. In addition, the vial and packaging of these medicines will be clearly marked with a warning against use in patients with cow's milk allergy.

Please refer to the following website in EMA for details:

http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Lactose_of_bovine_origin_31/Recommendation_provided_by_Pharmacovigilance_Risk_Assessment_Committee/WC500230921.pdf

In Hong Kong, there are 8 registered pharmaceutical products which are injectable methylprednisolone. Amongst them, only Solu Medrol 40mg Steril Mix-O/Act-O Vial (HK-00466) contains both methylprednisolone and lactose, which is registered by Pfizer Corporation Hong Kong Limited (Pfizer HK) and is a prescription only medicine.

In light of the above EMA's announcement, DH will follow-up with Pfizer HK and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please report any adverse events caused by drugs to the Pharmacovigilance 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)