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

電話號碼 Tel. No.: 2319 8458
查詢處 Enquiries (852) 2319 8458
傳真號碼 Faxline No. (852) 2603 4962

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

本署檔號 OUR REF.: DH DO PRIE/7-30/15

BY FAX

31 May 2013

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

Dr. Donald LI
President
Hong Kong Academy of Medicine
(Fax Number: 2505 5577)

Dear Dr. LI,

Magnesium Sulfate – Recommendation against Prolonged Use in Pre-term Labor

Your attention is drawn to the US Food and Drug Administration's (FDA) announcement with respect to the recommendation against using magnesium sulfate injection for more than 5-7 days to stop pre-term labor in pregnant women. This use of the drug is off-label, and is not an FDA-approved use of the drug. Magnesium sulfate is approved to prevent seizures in preeclampsia and for control of seizures in eclampsia in the US.

Administration of magnesium sulfate injection to pregnant women longer than 5-7 days may lead to low calcium levels and bone problems in the developing baby or fetus, including thin bones (osteopenia) and fractures. The shortest duration of treatment that can result in harm to the baby is not known. In light of this new safety information, the following information is being added to the drug label for Magnesium Sulfate Injection, USP 50% in the US:

1. A new Warning stating that continuous administration of magnesium sulfate injection beyond 5-7 days in pregnancy for the treatment of pre-term labor can cause low calcium levels and bone changes in the baby.
2. A new Teratogenic Effects section conveying the potential harm to developing babies by changing the Pregnancy Category to D from A. Pregnancy Category D means there is positive evidence of human fetal risk, but the potential benefits from using the drug in pregnant women may be acceptable in certain situations despite its risks.
3. A new Labor and Delivery section emphasizing that continuous administration of magnesium sulfate injection to treat pre-term labor is not approved and that the safety and efficacy of use for this indication are not established. When used in pregnant women for conditions other than its approved indication, magnesium sulfate injection should be administered only by trained obstetrical personnel in a hospital setting with appropriate obstetrical care facilities.

Please refer to FDA's website for details:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm354603.htm

In Hong Kong, there are three registered injectable pharmaceutical products containing magnesium sulfate. They are indicated for the treatment and prevention of hypomagnesaemia, pre-eclampsia and eclampsia. In view of FDA's recommendation, the matter will be discussed in the meeting of 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 encourage your members to 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). 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 drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms. Pamela LI)
for Assistant Director (Drug)