

衛生署藥物辦公室
藥物註冊及進出口管制部

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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Metoclopramide (Primperan) – important safety information

The Department of Health has been informed by Sanofi-Aventis HK Ltd. that products containing metoclopramide (Primperan) are contraindicated in subjects under 18 years of age, based on the evaluation conducted by the AFSSAPS (French Agency for the Safety of Healthcare Products). Metoclopramide is a dopamine antagonist neuroleptic with antiemetic properties.

Currently available data demonstrate that metoclopramide has an unfavorable risk profile with an increased risk of neurological effects, particularly extrapyramidal syndromes, in the whole pediatric population. This risk increases at high or repeated doses. Furthermore, data showing the clinical efficacy of metoclopramide are insufficient in nausea and vomiting, regardless of whether they are induced by chemotherapy. In addition, given that therapeutic alternatives are available, AFSSAPS considers that the benefit/risk ratio is no longer favorable in this population.

Metoclopramide is still indicated in adults but product information and package leaflets have been reinforced in France with data regarding neurological and cardiovascular risks.

In Hong Kong, Primperan Inj 10mg/2ml (HK-07173) and Primperan Tab 10mg (HK-07177) are registered by Sanofi-Aventis HK Ltd. and are prescription-only medicines. According to Sanofi-Aventis HK Ltd., the application for change of the product information in HK would be submitted once such amendment is approved in France. Department of Health will keep vigilant against any updated safety news of the drug.

Please report any adverse events caused by the drugs to the Adverse Drug Reaction Monitoring Unit of Department of Health (tel. no.: 2319 2920, fax: 2147 0457 or email: adr@dh.gov.hk). For details, please refer to the website: <http://www.drugoffice.gov.hk> at Drug Office under “Reporting an Adverse Drug Reaction”.

Yours sincerely,

(K. W. LAU)
for AD(D)