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(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

20 Sep 2024

Dear Healthcare Professionals,

Plaquenil® (Hydroxychloroquine sulfate): Risk of major congenital malformations and new risks of phospholipidosis and aggravation of myasthenia gravis symptoms

Your attention is drawn to the Singapore Health Sciences Authority's (HSA) announcement that a Dear Healthcare Professional Letter has been issued by Sanofi-Aventis Pte Ltd to inform healthcare professionals that the Huybrechts study published in 2021 suggested a small increase in the relative risk of major congenital malformations associated with the use of hydroxychloroquine in the first trimester of pregnancy, especially when used at a high daily dosage (≥ 400mg daily)..

Healthcare professionals are advised to avoid prescribing daily doses of ≥ 400mg in the first trimester of pregnancy except when, in the judgement of the healthcare professional, the individual's benefits outweigh the risks. It is also advisable to closely monitor the pregnancy, especially during the first trimester, for early detection of major congenital malformations. If there is no alternative treatment to hydroxychloroquine, the lowest effective dose should be used.

In addition, new risks of phospholipidosis and aggravation of myasthenia gravis symptoms have been reported with the use of hydroxychloroquine. Healthcare professionals are advised to discontinue hydroxychloroquine in patients if cardiac, renal, muscular or nerve toxicity is suspected or if aggravation of myasthenia gravis symptoms is suspected. The local package insert of Plaquenil® is being updated to include these information.

Please refer to the following website in HSA for details:
https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/plaquenil--(hydroxychloroquine-sulfate)---risk-of-major-congenital-malformations-and-new-risks-of-phospholipidosis-and-aggravation-of-myasthenia-gravis-symptoms

In Hong Kong, there are 5 registered pharmaceutical products containing hydroxychloroquine. All products are prescription-only medicines. So far, the Department of Health (DH) has received 9 cases of adverse drug reaction with regard to hydroxychloroquine, but these cases were not related to congenital malformations, phospholipidosis and aggravation of myasthenia gravis symptoms. Avoidance in pregnancy has already been included in the package insert of Hong Kong registered hydroxychloroquine products. Risk of aggravation of myasthenia gravis symptoms is documented in overseas reputable drug references such as the "Martindale: The Complete Drug Reference". In light of the above HSA's announcement, the DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. 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 Clinical Trials and 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,

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(Terence MAN)
for Assistant Director (Drug)