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

20 Nov 2024

Dear Healthcare Professionals,

Promethazine hydrochloride (Phenergan) not to be used in children under 6

Your attention is drawn to the Australia Therapeutic Goods Administration's (TGA) announcement that health professionals and consumers are advised that the oral antihistamine promethazine hydrochloride, sold as Phenergan and other generic brands, should not be used in children under 6 years of age.

This updated advice follows a TGA investigation and advice from the Advisory Committee on Medicines (ACM) in 2022, with warnings published in a previous Medicines Safety Update: first-generation oral sedating antihistamines - do not use in children.

The pharmaceutical company Sanofi-Aventis Healthcare requested the latest updates to its Product Information (PI), Consumer Medicine Information (CMI) and product label for its product Phenergan, following an internal investigation prompted by the ACM advice.

The PI and CMI documents have been updated to include the risks of psychiatric and central nervous system side effects in children under 6, including hyperactivity, aggression and hallucination. When high doses are given, these children may also experience difficulties in learning and understanding, including reversible cognitive deficit and intellectual disability.

Sanofi-Aventis Healthcare's benefit-risk review of the cumulative safety data in children between 2 to 5 years of age (inclusive) found that the cumulative weight of evidence was sufficient to support a causal association between promethazine (and combinations) and safety concerns relating to psychiatric and central nervous system events.

Phenergan is used to treat a range of conditions including allergies, hayfever and nausea, as well as for short-term sedation.

There are almost 50 other brands of oral promethazine hydrochloride on the Australian market and the sponsors of these products will also be required to update their PI and CMI documents, and product labelling. Oral promethazine products are currently scheduled S3, which means they can be sold over-the-counter with advice from a pharmacist.

Health professionals should be alert to the updated advice and appropriately counsel parents and carers who may intend to use Phenergan or another oral promethazine product in a child under 6 years old. These parents and carers should be directed to alternative products.

The TGA expects there will be a time lag before all products available in pharmacies will have updated package labelling. In the interim, the updated advice to not use oral promethazine medicines in children under the age of 6 years applies across all products.

At this stage, the updated advice does not apply to the single intravenous form of promethazine hydrochloride on the Australian market, noting that this product is only available with a prescription from a doctor.

Please refer to the following website in TGA for details:
https://www.tga.gov.au/news/safety-updates/promethazine-hydrochloride-phenergan-not-be-used-children-under-6

In Hong Kong, there are 236 registered oral pharmaceutical products containing promethazine. So far, with regard to promethazine, the Department of Health (DH) has received 5 cases of adverse drug reaction, but these cases were not related to psychiatric and central nervous system event in children under the age of 6. Related news was previously issued by the TGA, and was posted on the Drug Office website on 13 Jul 2022. In light of the above TGA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

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,

(Terence MAN)
for Assistant Director (Drug)