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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.)

22 Jul 2026

Dear Healthcare Professionals,

Domperidone: New contraindication in patients with phaeochromocytoma due to the risk of severe hypertension

Your attention is drawn to the following United Kingdom Medicines and Healthcare products Regulatory Agency's (MHRA) announcement that the product information has been updated for all domperidone products, to include a contraindication for patients with confirmed or suspected phaeochromocytoma (a rare tumour of the adrenal gland), due to the risk of episodes of severe hypertension.

Advice for Healthcare Professionals:

- a small number of reports have been received relating to severe episodes of hypertension in patients with phaeochromocytoma (a rare tumour of the adrenal gland) following administration of domperidone
- domperidone is now contraindicated in patients with confirmed or suspected phaeochromocytoma
- patients with confirmed or suspected phaeochromocytoma should stop taking domperidone immediately and be switched to an alternative treatment
- be aware that administration of domperidone can unmask phaeochromocytomas. If a patient taking domperidone has an episode of severe hypertension, consider further investigations for phaeochromocytoma
- domperidone should be used at the lowest effective dose for the shortest possible duration and maximum treatment duration should not usually exceed 1 week
- for patients receiving palliative care, an individual benefit risk decision on treatment should be made in discussion with the patient

Advice for Healthcare Professionals to Provide to Patients:

- stop taking domperidone immediately if you have been diagnosed with phaeochromocytoma (a rare tumour of the adrenal gland) by your doctor. Speak to your doctor or pharmacist about alternative treatment options

- seek medical attention immediately if you experience symptoms of severe high blood pressure. Symptoms can include, but are not limited to: persistent headache, blurred vision, shortness of breath and chest pain

Background

Domperidone is a dopamine antagonist with anti-emetic properties. It is licensed for use in adults and in children 12 years and above. Phaeochromocytomas are rare tumours of the adrenal gland and are often diagnosed through incidental imaging.

A recent European review of safety data for domperidone identified an association between domperidone and episodes of severe hypertension in patients with phaeochromocytoma following a small number of reports of this event. As a result, recommendations have been made to update the product information to include a contraindication for use of domperidone in patients with phaeochromocytoma due to the risk of severe hypertension.

Domperidone and introduction of contraindication for use in phaeochromocytoma

The findings of the European review were considered by the UK's Pharmacovigilance Expert Advisory Committee (PEAG) of the Commission on Human Medicines (CHM) who agreed with the recommendations and advised that the MHRA inform healthcare professionals and patients of this new contraindication.

The MHRA has not received any UK Yellow Card reports of domperidone and severe hypertension in patients with phaeochromocytoma. Four reports were considered in the European review. Phaeochromocytomas themselves are rare with a global prevalence of 19.8 per 1,000,000 people. Total prescribing of domperidone averages 222,000 items per year across NHS England. There are existing restrictions on domperidone prescribing, see further detail below.

New advice when prescribing domperidone

Do not prescribe domperidone to patients with confirmed or suspected phaeochromocytoma as domperidone is now contraindicated in this patient population. If patients with confirmed or suspected phaeochromocytoma are taking domperidone, treatment should be discontinued immediately and the patient switched to an alternative treatment. Patients should be advised to seek medical attention immediately if they experience symptoms of severe high blood pressure. Symptoms can include, but are not limited to: persistent headache, blurred vision, shortness of breath and chest pain.

For patients receiving palliative care, an individual benefit risk decision on treatment should be made in discussion with the patient.

Reminder of existing domperidone advice

Healthcare professionals are reminded of the existing recommendations and restrictions on domperidone prescribing (See December 2019 Drug Safety Update).

- domperidone should be used at the lowest effective dose for the shortest possible duration and

maximum treatment duration should not usually exceed 1 week

- for adults and adolescents 12 years of age or older and weighing 35 kg or more, the recommended maximum dose in 24 hours is 30 mg (dose interval: 10 mg up to 3 times a day)
- domperidone is authorised for the relief of symptoms of nausea and vomiting only in adults and adolescents 12 years of age or older or weigh 35kg or more
- consider alternative treatments to domperidone in children younger than 12 years of age who need relief of symptoms of nausea and vomiting
- domperidone is contraindicated in people receiving other medications known to prolong QT interval or potent CYP3A4 inhibitors

Please refer to the following website in MHRA for details:
https://www.gov.uk/drug-safety-update/domperidone-new-contraindication-in-patients-with-phaeochromocytoma-due-to-the-risk-of-severe-hypertension

In Hong Kong, there are 41 registered pharmaceutical products containing domperidone and are prescription-only medicines. So far, the Department of Health (DH) has received one case of adverse drug reaction with regard to domperidone, but the case was not related to severe hypertension in phaeochromocytoma. Related news on the risk and restrictions of domperidone use was previously issued by various drug regulatory authorities, and was posted on the Drug Office website since 8 Mar 2012, with the latest update posted on 29 Oct 2022. Letters to inform local healthcare professionals were issued by DH on 8 Mar 2012, 10 Mar 2014, 19 Apr 2016 and 17 Dec 2019, and the Registration Committee of the Pharmacy and Poisons Board of Hong Kong (the Registration Committee) had discussed the risk and restrictions of domperidone use in Feb 2012, May 2014 and Jun 2020. In light of the above MHRA new contraindication for domperidone use in patients with phaeochromocytoma, the matter will be discussed by the Registration Committee.

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,

(Clive CHAN)
for Assistant Director (Drug)