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DRUG OFFICE

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28 Apr 2021

Dear Healthcare Professionals,

Polyethylene glycol (PEG) laxatives and starch-based thickeners: potential interactive effect when mixed, leading to an increased risk of aspiration

Your attention is drawn to the United Kingdom Medicines and Healthcare products Regulatory Agency's (MHRA) announcement that addition of a polyethylene glycol (PEG)-based laxative to a liquid that has been thickened with a starch-based thickener may counteract the thickening action, placing patients with dysphagia at a greater risk of aspiration.

Polyethylene glycol (PEG) laxative products treat constipation through an osmotic effect. They are indicated mostly for adults with some formulations also indicated for use in children. Some PEG laxative products such as Movicol, Macrogol 3350, and Moviprep are available in the form of a powder, which must be dissolved in liquid before administration.

Thickened liquids are usually taken by patients with dysphagia, including people who are elderly or have disabilities that affect swallowing. Thickening the liquid before swallowing improves bolus control and reduces the risk of aspiration, which can be life-threatening. There are two main types of thickening agents – a starch-based (for example, corn-starch) or a gum-based (xanthan gum). Most thickeners are classified as foods for special medicinal purposes and are used to thicken both liquids and foods to various consistencies. There are many different brands of thickeners available and they can be in the form of powder or a liquid. The recommendation to use a thickener should be based on the patient's degree of dysphagia (and potential risk of aspiration), the desired consistency required, the texture required, palatability, and other clinical considerations.

The Institute for Safe Medication Practices (ISMP) Canada issued a Safety Bulletin discussing the possible potential harmful interaction between PEG laxative and starch-based thickeners. One case report was identified where a patient was switched to a thickened diet for dysphagia. PEG-3350 was mixed with a starch-based pre-thickened juice. On day 2 of administration the patient showed possible signs of

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aspiration after swallowing the dose. The patient died a few hours later. Although the cause of death was difficult to establish due to the patients underlying medical conditions, aspiration was thought to have been a contributing factor.

Addition of a PEG laxative to a liquid that has been thickened with a starch-based thickener can produce a mixture that is thin and watery – undoing the intended act of thickening. Patients with dysphagia who swallow the thinner liquid are potentially at greater risk of aspiration.

Constipation and dysphagia coexist more commonly in the elderly and in people with disabilities that affect swallowing. Therefore these populations may be of particular risk if a PEG laxative is added to liquid thickened with starch. The MHRA is currently not aware of any case reports of this potential interaction in the United Kingdom. MHRA has requested that the manufacturers of United Kingdom PEG laxative products add information about the potential interactive effect to the Summary of Product Characteristics and the Patient Information Leaflet.

Advice for healthcare professionals:

- There have been reports of a possible potential harmful interaction between polyethylene glycol (PEG) laxatives and starch-based thickeners when they are mixed together.
- Combining the two compounds can counteract the thickening action and result in a thin watery liquid – patients with swallowing difficulties (dysphagia) are potentially at greater risk of aspiration of the thinner liquid.
- Avoid directly mixing together PEG laxatives and starch-based thickeners, especially in patients with dysphagia who are considered at risk of aspiration such as elderly people and people with disabilities that affect swallowing.

Please refer to the following website in MHRA for details:

<https://www.gov.uk/drug-safety-update/polyethylene-glycol-peg-laxatives-and-starch-based-thickeners-potential-interactive-effect-when-mixed-leading-to-an-increased-risk-of-aspiration>

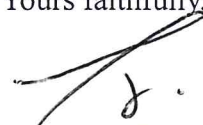
In Hong Kong, there are 5 registered pharmaceutical products containing polyethylene glycol (PEG) laxatives (including macrogol 3350 and macrogol 4000). All products are over-the-counter medicines. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to the macrogols. In light of the above MHRA's announcement, the matter will be discussed by 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 report any adverse events caused by drugs to the Adverse Drug Reaction 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

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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,

A handwritten signature in black ink, appearing to be 'J. LEE', written over a horizontal line.

(Joseph LEE)

for Assistant Director (Drug)