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Reaksi

DRUG SAFETY NEWS

Mission: This publication provides information and recommendations to healthcare professionals to enhance communication of drug safety updates, raise awareness of adverse drug reactions reported, and stimulate additional adverse drug reaction reporting.

This is a bimonthly publication by the Drug Safety Monitoring Centre, National Pharmaceutical Control Bureau (NPCB), Malaysia.

TO REPORT AN ADVERSE DRUG REACTION

Online

1. Visit www.bpfk.gov.my.
2. Click on ADR Reporting and Product Complaints.
3. Click to report as a healthcare professional online or via hardcopy.
4. Submit the form once completed.

Mail

1. Print out and complete the ADR form available from our website.
2. Mail or fax to:
   The Drug Safety Monitoring Centre, Centre for Post Registration of Products, National Pharmaceutical Control Bureau, Ministry of Health, PO Box 319, Jalan Sultan, 46730 Petaling Jaya, Selangor.

Telephone

03-7883 5400
(ext. 8460/ 8461/ 8463)

Fax

03-7956 7151

In This Issue:

Sodium Phosphate Oral Solutions and Enemas: Possible Harm Associated with Overdose

Background

In January 2014, the United States Food and Drug Administration (US FDA) issued a warning that using **more than one dose** of an over-the-counter (OTC) sodium phosphate product in 24 hours can cause rare but serious **kidney injury, arrhythmias**, or even **death**. In the US, OTC sodium phosphate products include oral solutions and enemas, which are used to treat constipation.

A review conducted by the US FDA revealed 54 such cases describing serious adverse events, involving 25 adults and 29 children. Ten of these cases were reported in the FDA Adverse Event Reporting System (FAERS) database and 44 were published in medical literature.

All the reports involved severe dehydration and/or electrolyte abnormalities, with serious complications as mentioned above. The severity of adverse events was similar regardless of the route of sodium phosphate administration. Almost 60% of the cases (32 cases) involved doses exceeding the recommended amount.

Local scenario

There are **six (6) related products** registered in Malaysia as listed in **Table 1**, all containing a **combination** of sodium phosphate and sodium biphosphate.

These products are generally indicated as laxatives for the relief of occasional constipation, or as purgatives used in bowel cleansing regimens to prepare patients for colonic surgery, x-rays or endoscopic examination.

The package inserts (PIs) for all the products registered in Malaysia adequately address this safety issue. Please refer to the specific PIs for detailed prescribing information.

Previously in **2009**, the NPCB published a safety communication regarding the **risk of acute phosphate nephropathy** with use of oral sodium phosphate products for bowel cleansing prior to medical procedures.

Information from the Ministry of Health Drug Formulary

Prescriber category:

- **Category A** (to be prescribed by specialists only)

Approved indications for use in MOH facilities:

- **Bowel cleansing** before colonic surgery, colonoscopy or radiology examination.
- It is **not to be used** for treatment of constipation.

Table 1: Sodium phosphate/ sodium biphosphate oral solutions and enemas registered in Malaysia

Brand Name	Registration No.	Product Registration Holder
Fleet Ready-to-use Enema	MAL19912389X	Pharmaforte (Malaysia) Sdn. Bhd.
Fleet Ready-to-use Enema for Children	MAL19912390X	
Fleet Phospho-soda Oral Saline Laxative Ginger Lemon Flavor	MAL20051384XR	
Colclean Solution	MAL07010931X	
Jojo Enema	MAL19911214XC	Jaya Medi Supply
Unima Enema	MAL20002265X	Medispec (M) Sdn. Bhd.

Adverse Drug Reaction (ADR) Reports

Since year 2000, the Drug Safety Monitoring Centre, NPCB, has received **12 ADR reports** comprising **27 adverse events** including generalised weakness (3 events), hypocalcaemia, numbness, tremor (2 events each), blood creatinine increased, pulmonary oedema, hypertension, ankle oedema, rectal bleeding, hyperphosphataemia, rash, vomiting, diarrhoea, and body ache.

All reports involved use for bowel cleansing procedures with patients ranging in age from 41 to 76 years. Of the 12 reports received, **ten (10)** were from **government facilities** and **two** from **private hospitals**. However, under-reporting of ADRs is suspected as data shows that usage of these products is almost **six times higher** in the **private sector** as compared to government facilities.

Risk factors for adverse events:

- Age ≤5 years or >55 years.
- Dehydration, hypovolemia or decreased intravascular volume.
- Underlying kidney disease, decreased bowel transit time, bowel obstruction, or active colitis.
- On concomitant medications that affect renal perfusion or function (e.g.: diuretics, ACEIs, ARBs, or NSAIDs).

Advice for Healthcare Professionals:

- Do not exceed the maximum recommended dose of sodium phosphate for both children and adults.
- Avoid concomitant treatment with other products/ laxatives containing sodium phosphate.
- Rectal forms of sodium phosphate **should not** be considered safer than oral forms.
- Contraindication: **Rectal** sodium phosphate products should not be used in children younger than **2 years**.
- Caution when recommending these products to patients with **risk factors** as mentioned above.
- Monitoring: Assess serum **electrolytes and renal function** in patients at higher risk of product-related adverse events.
- **Please report** all suspected adverse events involving sodium phosphate products to the NPCB.

Counselling Points for Patients/ Caregivers:

- Ensure **adequate hydration** before and during product use.
- **Do not** use more than one dose in 24 hours, even if there is no bowel movement after a single dose.
- **Do not** give the **rectal** products to children aged **<2 years**.
- **Do not** give the **oral** products to children aged **≤5 years** without consulting a healthcare professional.