

# Sodium Phosphate/Sodium Biphosphate, Enema

## Safety Considerations

### July 2013

VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives

#### BACKGROUND<sup>1-8</sup>

In the VA, sodium phosphate/sodium biphosphate enema is available for use in bowel preparation prior to a procedure or for the management of constipation. On March 26, 2013, the PBM VA Center for Medication Safety issued a National PBM Bulletin in response to a fatality in a patient administered several doses of sodium phosphate/sodium biphosphate enema in less than 12 hours for the management of severe constipation. Reports of severe adverse events resulting in severe electrolyte imbalance (hypernatremia, hyperphosphatemia, hypocalcemia, hypokalemia), dehydration and hypovolemia, tetany, QT prolongation, seizures, coma, and death are rare, but have been reported in the literature. An increased risk for severe adverse events or mortality may be associated with gastrointestinal disorders causing increased retention of enema contents in gut, patients with chronic renal failure, advanced age, and number of doses administered exceeding one within 24 hours.

#### CONTRAINDICATIONS<sup>1,9</sup>

- Do not use for constipation in patients aged  $\geq 70$  years
- Congestive heart failure
- Clinically significant impairment of renal function (eGFR  $< 30$  ml/min)
- Known or suspected gastrointestinal obstruction
- Megacolon (congenital or acquired)
- Paralytic ileus
- Perforation
- Active inflammatory bowel disease
- Imperforate anus
- Dehydration
- Generally, in cases of increased absorption capacity or decreased elimination
- Hypersensitivity to any product ingredients

#### PRECAUTIONS<sup>1,9</sup>

Use with caution in patients:

- With impaired renal function (eGFR 30 to 60 ml/min) or other comorbidities, such as gastrointestinal (including dysmotility, colonostomy), hepatic (including ascites), neurologic, cancer, pulmonary or cardiovascular disorders
- Taking medications known to affect renal perfusion or function, or hydration status
- With pre-existing electrolyte disturbances or who are taking diuretics or other medication which may affect electrolyte levels
- Who are taking medications known to prolong the QT interval
- More than 64 years of age or less than 6 years old
- Who are pregnant or nursing a baby
- Patients with conditions that may predispose to dehydration or those taking medications that may decrease glomerular filtration rate, such as diuretics, angiotensin-converting enzyme inhibitors (ACEIs), angiotensin II receptor antagonists (ARBs), or nonsteroidal anti-inflammatory drugs (NSAIDs), should be assessed for hydration status prior to use and managed appropriately

#### SAFETY CONSIDERATIONS FOR DOSAGE AND ADMINISTRATION<sup>1,10</sup>

- Administration of more than one enema in 24 hours, particularly in patients with constipation, risk factors for electrolyte disturbances and comorbidities, can be harmful and has resulted in death.
- In those cases where complications have been reported, overdoses are often involved.
- No other sodium phosphates preparation including sodium phosphates oral solution or tablets should be given concomitantly.
- Use of sodium phosphate enemas for chronic management of constipation is not recommended. If an enema is indicated for management of severe constipation (after alternate treatment options have been attempted), consider using warm water enemas or mineral oil enemas (i.e., following disimpaction) before considering sodium phosphate enemas. These treatments may have the potential for toxicity if not used appropriately, with recommendations not to exceed more than one per 24 hours. If a sodium phosphate enema is used for severe constipation, it is recommended that no more than one dose be administered per 24 hour period, for no more than 3 days.

#### References

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