NEW ZEALAND DATA SHEET

PHOSPHO-SODA oral solution

[Monobasic sodium phosphate dihydrate and Dibasic sodium phosphate dodecahydrate]

1 PRODUCT NAME

PHOSPHO-SODA 24.4g/10.8g oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 45mL of PHOSPHO-SODA contains 18.8g monobasic sodium phosphate (as 24.4g monobasic sodium phosphate dihydrate) and 4.3g dibasic sodium phosphate (as 10.8g dibasic disodium phosphate dodecahydrate).

Excipient(s) with known effect:

PHOSPHO-SODA has a sodium content of 5.0g per 45mL (11.11% w/v).

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution. PHOSPHO-SODA is a, clear, colourless, ginger-lemon flavoured, aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For use as part of a bowel cleansing regimen in preparing the patient for surgery or for preparing the colon for x-ray or endoscopic examination.

4.2 Dose and method of administration

Also refer to section 4.3 and section 4.4 of this data sheet.

This product normally produces a bowel movement in half to 6 hours. Patients should be warned to expect frequent liquid stools.

PHOSPHO-SODA should not be taken by children under 12 years of age.

Adults and children over 12 years of age:

The recommended dosage for adults and children over 12 years of age and over is 45mL (one bottle full) and repeated 10 to 12 hours later. The intake of "clear liquid" is an essential part of this regimen.

Please note that, on the day before the procedure, the patient should only take Clear Liquids (see below) for breakfast, lunch and dinner and between doses.

No solid food, milk or milk products should be taken on the day before the procedure. Please note that the patient should not drink anything coloured red or purple.

Depending on whether the medical procedure is intended to be performed at early morning, mid-morning or later, two alternative dosage regimens are set out below:

Early Morning Procedure

The first dose is taken at 7 am on the day before the procedure. The second dose is taken at 7 pm on the evening before the procedure.

Mid-Morning (or later) Procedure

The first dose is taken at 7 pm on the evening before the procedure. The second dose is taken at 7 am (or at least 3 hours before leaving for the appointment) on the morning of the procedure .

First dose

To be taken as follows:

- Mix 15mL (one third of the bottle) of PHOSPHO-SODA into a full glass (approximately 250mL) of Clear Liquids (see list below) and drink.

Repeat two more times within the next 20 minutes.

Between Doses

Between the first and second doses, the patient should drink at least three more glasses (approximately 250mL each) of Clear Liquids or more if desired to prevent dehydration and to ensure that their bowel remains easily examinable for the procedure.

Second Dose

The second dose is taken as follows:

- Mix 15mL (one third of the bottle) of PHOSPHO-SODA into a full glass (approximately 250mL) of Clear Liquid (see list below) and drink.

Repeat two more times within the next 20 minutes.

Important

The intake of Clear Liquid is an essential part of this regimen. Please refer to Clear Liquids list below.

"Clear Liquids" list

Beverages

- Water, tea or coffee (no milk or non-dairy creamer). Sweeteners are acceptable,
- Carbonated or non-carbonated soft drinks (not coloured red or purple),
- Fruit flavoured cordials (not coloured red or purple),
- Strained fruit juices without pulp,
- Do not drink any alcoholic beverages,
- Soups,
- Strained low sodium chicken or beef soup without solid material.

4.3 Contraindications

Administration of PHOSPHO-SODA is contraindicated in:

- children under 12 years of age (particularly at risk of dehydration),
- in patients who have demonstrated hypersensitivity to the drug or its inactive ingredients,
- the event of nausea, vomiting and stomach pain
- patients with faecal impaction,
- paralytic ileus,
- bowel obstruction,
- active inflammatory bowel disease,
- hypomotility,
- congenital or acquired megacolon,
- imperforate anus,
- congestive heart failure,

- ascitic conditions,
- clinically significant impairment of renal function and potentially pre-existing fluid/electrolyte disturbances,
- primary hyperparathyroidism associated to hypercalcaemia
- patients at risk of dehydration due to altered senses and/or poor fluid intake.

PHOSPHO-SODA should not be used in combination with other laxatives containing sodium phosphate.

WARNING: Life threatening dehydration and/or electrolyte disturbances may occur in 'at risk' groups - see section 4.4.

4.4 Special warnings and precautions for use

PHOSPHO-SODA can only be used at the prescribed dosage and following instructions for use.

Severe and life-threatening disorders in elderly patients

Intake of PHOSPHO-SODA may rarely cause severe, life-threatening disorders in elderly patients. **A careful analysis of risks and benefits should be made in this group of patients before starting treatment with PHOSPHO-SODA.**

Special caution should be taken when prescribing PHOSPHO-SODA to patients with known interactions, and importance of adequate hydration should be emphasized. In risk patients (see sections 4.2 and 4.3), it is important to measure electrolyte levels before and after treatment.

Dehydration

This product is effective in the bowel from half an hour to 6 hours after intake. If no effect is seen in the bowel during the 6 hours following intake of PHOSPHO-SODA, administration should be discontinued immediately and a physician should be consulted, because there is a risk of dehydration.

Patients should be informed that stools will be more frequent and liquid.

Patients should be encouraged to drink as much liquid as possible to prevent dehydration. When too little liquid is drank when using a laxative, there is a risk of dehydration and hypovolaemia.

Dehydration and hypovolaemia resulting from use of a laxative may worsen if no adequate liquid is taken, if nausea or vomiting occur, when appetite is reduced, and when diuretics, ACE inhibitors, angiotensin receptor blockers, and NSAIDs are used, and may be associated with acute renal failure. Some rare cases of acute renal failure have been reported with laxatives such as sodium phosphate and PEG 3350.

At risk patients

Administer with caution to patients with cardiac conditions, latent risk of renal failure, acute myocardial infarction, unstable angina, electrolyte disorder, high risk of suffering electrolyte disorders (dehydration, gastric retention, colitis, inability to swallow liquid, or intake of drugs that may cause dehydration, weak or elderly people). In patients with clinically documented hypotension or hypotension associated to hypovolaemia, measurement of sodium, potassium, calcium, chloride, bicarbonate, phosphate, urea, nitrogen, and creatinine levels before and after treatment should be considered.

Frequent, long-term use of laxatives may cause habituation to laxatives and intestinal problems.

Children with megacolon are susceptible to dehydration resulting from acutely increased serum sodium levels.

Electrolyte disorders

There is a risk of increased sodium and phosphate levels and decreased potassium and calcium levels and, thus, of hyperphosphataemia, hypernatraemia, hypocalcaemia, hypokalaemia, and acidosis.

A slightly prolonged QT interval resulting from an electrolyte imbalance, such as hypocalcaemia and hypokalaemia, is seen in some cases. These changes are not clinically significant.

Hypomotility

Use with caution in patients with intestinal hypomotility, undergoing gastrointestinal surgery, or with other conditions that may cause hypomotility problems. In patients who have undergone colostomy or ileostomy or on a low salt diet, the preparation should be used with caution, because electrolyte balance disorders, dehydration, or an acid-base balance disorder may occur.

Nephrocalcinosis

Rare cases of nephrocalcinosis combined with transient renal failure and disorder have been reported with use of sodium phosphate for bowel cleansing. Phosphate-induced nephropathy, sometimes leading to irreversible chronic renal failure, has rarely been reported with use of the product for bowel cleansing. Potential risk factors for acute phosphate-induced nephropathy include advanced age, inadequate hydration during use of laxatives, treatment with an ACE inhibitor, sartans, diuretics, or NSAIDs, and presence of hypertension or atherosclerosis.

Most reports were of elderly female patients who were taking antihypertensives or other drugs, such as diuretics or NSAIDs, which may cause dehydration. Hydration status of patients at risk of dehydration or taking drugs that decrease glomerular filtration rate, such as ACE inhibitors or angiotensin receptor blockers, should be assessed before laxative preparations are used, and adequate management should be provided.

Lesions

In exceptional cases, punctiform lesions are seen in the rectosigmoid region during endoscopic examination. These are lymphoid follicles or mild inflammatory infiltrates or epithelial congestions/changes seen during colon preparation. These abnormalities are not clinically significant and resolve spontaneously without treatment.

Use in Diabetic Patients:

As the liquid diet during the period of administration and prior to bowel surgery, x-ray of the colon or colonoscopy may affect the diabetic patients' glucose blood levels, adjustment of their insulin or oral anti-diabetic medication may be necessary.

4.5 Interaction with other medicines and other forms of interaction

Caution should be taken when patients are taking antihypertensives, calcium channel blockers, diuretics, lithium, or other drugs that may impair electrolyte balance, because they may cause hypokalaemia, hypocalcaemia, hyperphosphataemia, hypernatraemia, and acidosis.

Use with caution in patients who are taking drugs for hyperparathyroidism.

Drug absorption from the bowel may be delayed or completely interrupted when PHOSPHO-SODA is used. Activity of some commonly used oral drugs (including, amongst others, oral contraceptives, anticonvulsants, antidiabetics, and antibiotics) may be decreased or completely annulled.

Administer with caution to patients taking other drugs that prolong the QT interval.

Concomitant administration with other sodium phosphate preparations is contraindicated.

Concurrent administration of polyethylene glycol bowel cleansing preparations and PHOSPHO-SODA may be dangerous and is not recommended (see section 4.8).

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no clinical data on use of PHOSPHO-SODA in pregnant women, nor animal studies on the effect on pregnancy, embryofoetal development, delivery, and postnatal development. The potential risk for humans is not known. PHOSPHO-SODA should not be used during pregnancy unless strictly necessary.

Breastfeeding

It is unknown whether PHOSPHO-SODA is excreted in human milk. Since sodium phosphate may be excreted in human milk, it is recommended to extract and discard the milk from the first dose to 24 hours after the second dose of the bowel cleansing solution. Breast-feeding should be discontinued for 24 hours after the second dose of PHOSPHO-SODA.

Fertility

No information

4.7 Effects on ability to drive and use machines

PHOSPHO-SODA may cause dizziness, probably as a result of dehydration.

4.8 Undesirable effects

Within each frequency group, undesirable effects are classified by decreasing severity: Very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1000, <1/100); rare (≥1/10.000, <1/1,000); very rare (<1/10.000); not known (cannot be estimated from the available data).

Blood and lymphatic system disorders: very rare: hypotension

Immune system disorders: very rare: hypersensitivity.

Metabolic and nutrition disorders: uncommon: dehydration; very rare: hyperphosphataemia, hypocalcaemia, hypokalaemia, hypernatraemia, metabolic acidosis, tetany.

Nervous system disorders: very common: dizziness; headache; very rare: paraesthesia, loss of consciousness.

Cardiac disorders: very rare: myocardial infarction, arrhythmia, slight QT interval prolongation.

Gastrointestinal disorders: very common: nausea, abdominal pain, bloating, diarrhoea; common: vomiting; uncommon: unrelated punctiform (single or multiple) lesions are sometimes seen in the colonoscopy in the rectosigmoid region. These abnormalities are not clinically significant and resolve spontaneously without treatment.

Skin and subcutaneous tissue disorders: very rare: allergic dermatitis.

Musculoskeletal and connective tissue disorders: very rare: cramps.

Renal and urinary disorders: very rare: acute renal failure, chronic renal failure; rare: nephrocalcinosis, acute nephropathy sometimes associated to irreversible chronic renal failure.

General disorders and administration site conditions: very common: tremors, asthenia; common: chest pain.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

Cases of hyperphosphataemia associated with hypocalcaemia, hypernatraemia, and acidosis has been reported when PHOSPHO-SODA is administered in excessive doses to children and patients with obstruction.

In the event of overdose or accidental intake, severe adverse reactions may occur, including dehydration, hypotension, tachycardia, bradycardia, tachypnoea, cardiac arrest, shock, respiratory failure, dyspnoea, seizures, paralytic ileus, anxiety, and abdominal pain. An overdose may cause increased serum sodium and phosphate levels. In these cases, hypokalaemia, hypocalcaemia, hyperphosphataemia, hypernatraemia, and acidosis may occur.

Cases of complete recovery after an overdose have been reported both in children accidentally given PHOSPHO-SODA and in patients with obstruction, including one with a six-fold overdose.

Recovery from toxicity due to overdose may normally be achieved with rehydration, although intravenous administration of 10% calcium gluconate is required in some cases

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: osmotically acting laxatives

ATC code: A06AD

PHOSPHO-SODA is a saline laxative that works by osmotic processes to increase fluid retention in small bowel lumen. The resultant fluid accumulation in the ileum causes distention and induces in turn bowel movement and evacuation. The start of these peristaltic movements depends on the patient and occurs 1 to 2 hours after administration.

5.2 Pharmacokinetic properties

Phosphate is partially reabsorbed from the intestinal tract. Most phosphate is filtered in glomeruli and is partially reabsorbed. Almost all phosphate reabsorbed is excreted in urine, and the rest in faeces.

Sodium is reabsorbed from the lumen of the colon in an amount proportional to concentration. With intake of 45 mL of PHOSPHO-SODA, change in serum level is very small.

Ninety minutes after intake of 45 mL, a mean increase of 2.2 mEq of sodium per litre is seen, corresponding to approximately 50 mg of Na per litre.

5.3 Preclinical safety data

No studies related to reproductive toxicity in animals have been conducted with PHOSPHO-SODA.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

PHOSPHO-SODA contains the following excipients:

- Purified Water
- Glycerol
- Saccharin sodium
- Sodium benzoate
- Ginger lemon flavour*

* ginger extract, alcohol, lime extract, citric acid, water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

PHOSPHO-SODA is available in 45mL bottles.

6.6 Special precautions for disposal <and other handling>

This product must be diluted with water before use.

7 MEDICINE SCHEDULE

Pharmacist Only Medicine.

8 SPONSOR

Pharmaco (NZ) Ltd
4 Fisher Crescent
Mt Wellington
Auckland 1060
Telephone: 09 377 3336

9 DATE OF FIRST APPROVAL

29/07/1993

10 DATE OF REVISION OF THE TEXT

July 2017

[SPC Sept 2015]

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Reformatted to new SPC format
4.7	Addition of information about effects on driving and using machinery
6.3	Change of shelf life from 30 months to 36 months