

PRODUCT INFORMATION FLEET® PHOSPHO-SODA®

NAME OF DRUG:

Each 5mL of Fleet Phospho-soda contains sodium phosphate monobasic 2.4g and sodium phosphate dibasic 0.9g.

DESCRIPTION:

Fleet Phospho-soda is a stable, clear, colourless, buffered, ginger-lemon flavoured, aqueous solution.

It contains the following excipients: purified water, glycerol, saccharin sodium, sodium benzoate, ginger lemon flavour wofn 034223.

Fleet Phospho-soda has a sodium content of 5g per 45mL (11.11% w/v).

PHARMACOLOGY:

Fleet Phospho-soda is a saline mixture which acts by osmotic processes to increase fluid retention in the lumen of the small intestine. Fluid retention in the ileum produces distension, in turn promoting peristalsis and evacuation. It has a purgative effect. Individual responses vary. It usually acts shortly after 30 minutes but may take as long as 6 hours. If there has been no bowel movement within 6 hours of taking Fleet Phospho-soda, instruct the patient to stop use and contact a doctor immediately as dehydration could occur.

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.

CONTRAINDICATIONS:

Administration of Fleet-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, patients with faecal impaction, paralytic ileus, bowel obstruction, active inflammatory bowel disease, hypomotility, Hirschsprung's disease (congenital megacolon), imperforate anus, congestive heart failure, ascitic conditions, clinically significant impairment of renal function and potentially pre-existing fluid/electrolyte disturbances, and patients at risk of dehydration due to altered senses and/or poor fluid intake.

WARNING:

Life threatening dehydration and/or electrolyte disturbances may occur in 'at risk' groups – see CONTRAINDICATIONS & PRECAUTIONS.

Nephrocalcinosis associated with transient renal insufficiency and renal failure has been very rarely reported in patients using sodium phosphates for bowel cleansing; the majority of these reports occurred in elderly female patients taking drugs to treat hypertension or other drug products, such as diuretics or NSAIDs, that may result in dehydration. Patients with conditions that may predispose to dehydration or those taking medications which may decrease glomerular filtration rate, such as diuretics, angiotensin converting enzyme inhibitors (ACE-Is), angiotensin receptor blockers (ARBs), or non-steroidal anti-inflammatory drugs (NSAIDs) should be assessed for hydration status prior to use of purgative preparations and managed appropriately. Care should be taken to prescribe Fleet Phospho-soda per recommendations with a particular attention to known contraindications and adequate hydration.

PRECAUTIONS:

Fleet Phospho-soda, which contains 4.82 mEq sodium and 12.45 mEq phosphate per mL, should be used with **extreme caution**, in the elderly, the frail or debilitated, patients with colostomy and patients on a low salt diet, as they are particularly at risk. These patients should receive additional fluids by mouth, both prior to, and after administration of Fleet Phospho-soda, to ensure that dehydration does not occur. Close attention should be paid to their hydration status and their electrolyte levels (particularly potassium, calcium and phosphorus) should be monitored. Patients undergoing major bowel procedures, who are on nil by mouth for significant periods of time, should have their electrolytes monitored and receive intravenous fluids containing potassium and calcium, prior to surgery.

Use with caution in patients taking diuretics and in patients using medicines known to prolong the QT interval.

Concurrent administration of polyethylene glycol bowel cleansing preparations and Fleet Phospho-soda may be dangerous and is not recommended (see ADVERSE REACTIONS).

Extra time should be taken to explain dosage instructions to the elderly and those patients who may be at risk. Patients should be advised not to use Fleet Phospho-soda when nausea, vomiting or abdominal pain are present, unless directed by a physician.

Use in pregnancy:

Because of potential harm to the foetus from phosphate absorbed across the placenta, the use of this product is not recommended in pregnant women unless the probable clinical benefit outweighs the possible risk.

Use in lactation:

Because of potential harm to the infant from phosphate excreted in breast milk, the use of this product is not recommended in nursing mothers unless the probable clinical benefit outweighs the possible risk.

Use in diabetics:

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.

Interactions with other drugs:

Use with caution in patients taking calcium channel blockers, diuretics, angiotensin converting enzyme inhibitors (ACE-Is), angiotensin receptor blockers (ARBs), non-steroidal anti-inflammatory drugs (NSAIDs), and lithium preparations or other medication that might affect electrolyte levels, as hyperphosphataemia, hypocalcaemia, hypernatraemic dehydration and acidosis may occur. Concurrent administration of polyethylene glycol bowel cleansing preparations and Fleet Phospho-soda may be dangerous and is not recommended (see ADVERSE REACTIONS).

ADVERSE REACTIONS:

Oral sodium phosphate products can cause dehydration (between 1 and 4 L fluid loss, hyperphosphataemia, hypocalcaemia, other electrolyte abnormalities and associated complications.

Severe adverse reactions (serious serum electrolyte disturbances and hypokalaemia) and fatalities have been reported in patients who belonged to the 'at risk' groups (the elderly, the frail, those with renal impairment and cardiac failure), patients with known contraindications (including children under 12 years) and concurrent administration with polyethylene glycol bowel cleansing preparation.

Transient hyperphosphataemia, some degree of hypovolaemia and significant differences in serum electrolyte levels have been noted in clinical trials. In healthy and fit patients these have returned to initial pre-treatment levels within 24 hours.

In addition, there have been occasional reports of nausea, vomiting, abdominal pain, bloating, fatigue, anal irritation, allergic reactions with or without rash, hunger and sleep loss.

DOSAGE AND ADMINISTRATION:

Refer to the **PRECAUTIONS** and **CONTRAINDICATIONS** sections of this product information.

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.

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

Fleet Phospho-soda should not be taken by children under 12 years of age.

Adults and children 12 years of age & over:

The recommended dosage for adults and children 12 years of age & over is 45mL (one full bottle) and repeated 10 to 12 hours later. The intake of *Clear Liquids* 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 7a.m. on the day before the procedure. The second dose is taken at 7 p.m. on the evening before the procedure.

Mid-morning (or later) procedure:

The first dose is taken at 7p.m. on the evening before the procedure. The second dose is taken at 7a.m. (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 Fleet 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 Fleet 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.

OVERDOSAGE

If overdose occurs, for advice contact a Poisons Information Centre on 13 11 26 (Australia) or 0800 764 766 (New Zealand).

Recovery from the toxic effects of accidental excess ingestion can normally be achieved by rehydration, although the intravenous administration of 10% calcium gluconate may be necessary if there is significant hypocalcaemia or tetany has occurred.

PRESENTATION

Fleet Phospho-soda is available in 45mL bottles, each containing sodium phosphate monobasic 21.6g and sodium phosphate dibasic 8.1g.

Poisons schedule: Schedule 3 – Pharmacist Only

Shelf life and storage conditions:

3 years when stored below 25°C

Registration number:

AUST R 43656

Name of the sponsor:

C.B.Fleet Co. (Aust) Pty.Ltd.

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TGA Approval date: 24 June 2010