

**IMPORTANT
PRESCRIBING
INFORMATION**

Re: **Fleet® Prep Kit 1 – Decision to Discontinue Sale**
Fleet® Prep Kit 3 – Will Continue to be Sold

Dear U.S. Healthcare Professional:

The purpose of this letter is to notify you that, effective February 13, 2009, C.B. Fleet Company, Inc., doing business as Fleet Laboratories, will discontinue further sale of its Fleet® Prep Kit 1 product. **PLEASE NOTE THAT THIS IS NOT A RECALL AND DOES NOT AFFECT PRODUCT CURRENTLY IN DISTRIBUTION. Fleet® Prep Kit 3 will continue to be sold.**

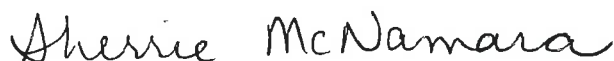
The decision to discontinue Fleet® Prep Kit 1 is related solely to the inability to continue to manufacture the bisacodyl suppository contained in the Fleet® Prep Kit 1 product. This decision is not related to Fleet's recent recall of its Fleet® Phospho-soda® and Fleet® Phospho-soda® EZ-Prep® Bowel Cleansing System products. FDA has indicated that both Prep Kit products will be included as bowel cleansing kits in the Final Monograph on OTC Laxative Drug Products for Human Use when rule is published, [see FDA Docket 78N-036L/CP0008 – Letter dated October 26, 1989, and Letter dated January 16, 2001, comment PRC2] and that the Fleet® Prep Kits were not subject to the December 11, 2008, FDA MedWatch Safety Alert on OSP Oral Sodium Phosphate Products for Bowel Cleansing.

As noted, Fleet® Prep Kit 3 will continue to be sold. Fleet® Prep Kit 3 is identical to Fleet® Prep Kit 1 in indication of use – “For use as a bowel cleansing regimen in preparing patients for surgery or for preparing the colon for x-ray or endoscopic examination” and similar in contents: both products contain one 45 mL (1.5 fl. oz.) bottle of Fleet® Phospho-soda®, 4 Fleet® bisacodyl tablets and directions for use and a Patient Information Sheet - **the only difference is that Fleet® Prep Kit 3 contains a 10 mg bisacodyl enema, rather than a 10 mg bisacodyl suppository, for use as the final cleansing step.**

As proper use of this product is important for patient safety, and the effectiveness of the product in preparing patients for medical procedures, we are enclosing a copy of the professional labeling for Fleet® Prep Kit 3 for your information.

Should you have any questions about this letter or Fleet® Prep Kit 3, please do not hesitate to contact us at MedicalAffairs@cbfleet.com or 1-866-255-6960.

Sincerely,



Sherrie McNamara, R.N., B.S.N., M.B.A.
Director of Medical Affairs and Product Safety

FLEET® PREP KIT 3

Bowel Evacuant

COMPOSITION

FLEET® Prep Kit 3 contains:

1. FLEET® Phospho-soda® Oral Saline Laxative—1.5 fl. oz. (45 mL).
2. FLEET® Bisacodyl Tablets—4 laxative tablets.
3. FLEET® Bisacodyl Enema 1.25 fl. oz. (37 mL)—1 laxative enema. Active Ingredient: Each 30-mL delivered dose contains 10 mg bisacodyl USP.
4. 1 Patient Instruction Sheet.
5. 1 Patient Information Sheet.

FLEET® Prep Kit 3 should not be used in children under 18 years.

PHARMACOKINETICS

Caswell M, Thompson WO, Kanapka JA, Galt DJB. The time course and effect on serum electrolytes of oral sodium phosphates solution in healthy male and female volunteers. Can J Clin Pharmacol 14(3):e260-e274, 2007

http://www.cjcp.ca/pdf/CJCP07005e260_e274.pdf

Each recommended dose (1.5 fl. oz.) (45 mL) of FLEET® Phospho-soda® oral saline laxative contains 5004 mg sodium.

ACTIONS AND USES

Bowel Cleansing System

INDICATIONS

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

PROFESSIONAL USE INFORMATION WARNINGS

RENAL DISEASE AND ACUTE PHOSPHATE NEPHROPATHY:

There have been reports of renal failure and acute phosphate nephropathy (also known as nephrocalcinosis) in patients who received oral sodium phosphates products (solution and tablets) for bowel cleansing prior to colonoscopy and surgery. These cases often resulted in permanent impairment of renal function, with some patients requiring dialysis and/or transplant. The majority of these reports occurred in patients taking hypertension medications such as angiotensin converting enzyme inhibitors (ACE-Is), angiotensin receptor blockers (ARBs) or other drug products such as diuretics or non-steroidal anti-inflammatory drugs (NSAIDs). Patients at increased risk for acute phosphate nephropathy include those with conditions that affect renal perfusion or function or those taking medications which may decrease glomerular filtration rate, or predispose to dehydration, including diuretics, ACE-Is, ARBs, or NSAIDs. Patients at increased risk should be assessed for hydration status prior to use of purgative preparations and managed appropriately.

ELECTROLYTE DISORDERS: FLEET® Phospho-soda® has been associated with severe and potentially fatal cases of electrolyte disorders in elderly patients. The benefit/risk ratio of Fleet® Phospho-soda® needs to be carefully considered before initiating treatment in this at-risk population. Special attention should be taken when prescribing Fleet® Phospho-soda® to any patient with regard to known contraindications and risks, the importance of adequate hydration and, in at-risk populations (see below), the importance of also obtaining baseline and posttreatment serum electrolyte levels, and blood urea nitrogen and creatinine levels.

In all patients there is a risk of elevated serum levels of sodium and phosphate and decreased serum levels of calcium and potassium; consequently, hypernatremia, hyperphosphatemia, hypocalcemia, hypokalemia, and acidosis may occur.

OTHER IMPORTANT SAFETY INFORMATION:

Renal Impact: Sodium phosphate is known to be substantially excreted by the kidney, and the risk of adverse reactions with sodium phosphates may be greater in patients with impaired renal function. Since elderly patients are more likely to have impaired renal function, consider performing baseline and post-procedure labs (phosphate,

calcium, potassium, sodium, creatinine, GFR and BUN) in these patients (see WARNINGS).

Hypersensitivity Reactions: There have been reports of hypersensitivity reactions (e.g., rash, urticaria, pruritus, tongue edema, throat tightness, and paresthesia of the lips) associated with the use of marketed sodium phosphates products.

Aphthoid Lesions: Single or multiple aphthoid-like punctiform lesions located in the rectosigmoid region have been observed by endoscopy. These were either lymphoid follicles or discrete inflammatory infiltrates or epithelial congestions/ changes revealed by the colonic preparation. These abnormalities are not clinically significant and disappear spontaneously without any treatment.

Absorption of Medications: During the intake of Fleet® Phospho-soda® the absorption of drugs from the gastrointestinal tract may be delayed or even completely prevented. The efficacy of regularly taken oral drugs (e.g. oral contraceptives, antiepileptic drugs, antidiabetics, antibiotics) may be reduced or completely absent.

Concomitant Medications: NO OTHER SODIUM PHOSPHATES PREPARATIONS INCLUDING SODIUM PHOSPHATES-BASED ENEMAS OR TABLETS SHOULD BE GIVEN CONCOMITANTLY.

CONTRAINDICATIONS

Do not use in patients with

- Congestive heart failure
- Clinically significant impairment of renal function
- Ascites
- Known or suspected gastrointestinal obstruction
- Megacolon (congenital or acquired)
- Perforation
- Hyperparathyroidism
- Ileus
- Active inflammatory bowel disease; Crohn's disease; ulcerative colitis.

Do not use

- In children under the age of 18 years
- When abdominal pain, nausea, or vomiting are present
- If there is a hypersensitivity to the active ingredients or any of the excipients

PRECAUTIONS

Use with caution in patients who are

- Elderly
- Debilitated
- Taking medications known to affect renal perfusion or function, or hydration status
- Taking medications known to prolong the QT interval
- Taking parathyroid hormone medications
- On a low-salt diet
- Pregnant or nursing a baby

And in patients with

- Heart disease
- Arrhythmia
- Cardiomyopathy
- Recent myocardial infarction
- Unstable angina
- Prolonged QT interval
- An increased risk for underlying renal impairment
- An increased risk for, or pre-existing, electrolyte disturbances, including patients with
- Dehydration
- Inability to take adequate oral fluid
- Hypertension or other conditions in which the patients are taking products that affect electrolytes or may result in dehydration (see Hydration information below)
- Gastric retention, hypomotility disorders, history of gastric bypass/stapling surgery; or
- Colitis
- A colostomy or ileostomy

In at-risk patients, including elderly patients, the benefit/risk ratio of Fleet® Phospho-soda® needs to be carefully considered before initiating treatment. Consider obtaining baseline and post-procedure serum sodium, potassium, calcium, chloride, bicarbonate, phosphate, blood urea nitrogen and creatinine values. If any patient develops vomiting and/or signs of dehydration, measure post-procedure labs (phosphate, calcium, potassium, sodium, creatinine, GFR and BUN.) Care should be taken to prescribe Fleet® Phospho-soda® oral saline laxative as a bowel cleanser by volumes, not “by the bottle” (see OVERDOSAGE OR NO BOWEL MOVEMENT), per recommendations with a particular attention to known contraindications and adequate hydration (See DOSAGE AND ADMINISTRATION and INFORMATION FOR PATIENT).

Bisacodyl products may cause abdominal discomfort, faintness, and cramps. FLEET® Bisacodyl Tablets should be swallowed whole. Do not prescribe to patients who cannot swallow without chewing unless directed by a physician.

Store at temperatures not above 86°F (30°C)

HYDRATION

Additional liquids by mouth are recommended with all bowel cleansing dosages. Encourage patients to drink large amounts of clear liquids before and during the bowel preparation process, and after the procedure, in order to prevent dehydration. Before the procedure, the patient should begin drinking plenty of clear liquids, such as 36 to 48 fl. oz. of a carbohydrate-electrolyte solution; during the preparation the patient should drink a minimum of 72 fl. oz. of clear liquids; during the procedure it is recommended that intravenous fluids (500-1,000 mL) be administered; and after the procedure the patient should drink as much liquid as possible to help prevent dehydration. Inadequate fluid intake when using any effective purgative may lead to excessive fluid loss, possibly producing dehydration and hypovolemia. Dehydration and hypovolemia from purgation may be exacerbated by inadequate oral liquid intake, nausea, vomiting, loss of appetite, or use of diuretics, ACE-Is, ARBs, NSAIDs, and lithium or other medications that may affect electrolyte levels, and may be associated with acute renal failure. There have been reports of acute renal failure associated with bowel purgatives. Drinking large amounts of clear liquids (at least 72 fl.oz. during the bowel preparation process) also helps ensure that your patient’s bowel will be clean for the procedure. Instruct the patient to contact a physician if there is no bowel movement after six hours as electrolyte imbalance can occur. (See OVERDOSAGE OR NO BOWEL MOVEMENT below).

See individual listings for FLEET® Phospho-soda® Oral Saline Laxative, and FLEET® Bisacodyl Laxatives for additional warnings. PREP KITS SHOULD NOT BE USED IN CHILDREN UNDER 18 YEARS OF AGE.

OVERDOSAGE OR NO BOWEL MOVEMENT

Overdosage (including shorter time intervals between doses than recommended) or no bowel movement may lead to severe electrolyte disturbances, including hypernatremia, hyperphosphatemia, hypocalcemia, and hypokalemia, as well as dehydration and hypovolemia, with attendant signs and symptoms of these disturbances (such as metabolic acidosis, renal failure, and tetany). Certain severe electrolyte disturbances may lead to cardiac arrhythmia and death. The patient who has taken an overdose or who fails to have a bowel movement after six hours should be monitored carefully. Patients experiencing overdose or no bowel movement have presented the following symptoms; dehydration, hypotension, tachycardia, bradycardia, tachypnoea, cardiac arrest, shock, respiratory failure, dyspnoea, convulsions, ileus paralytic, anxiety, and pain. Overdoses or no bowel movement can also lead to elevated serum levels of sodium and phosphate and decreased levels of calcium and potassium.

In those cases, hypernatremia, hyperphosphatemia, hypocalcemia and hypokalemia may occur with resulting metabolic acidosis, renal failure, tetany and in severe cases, multi-organ failure, cardiac arrhythmia and death.

Treatment of electrolyte imbalance may require immediate medical intervention with appropriate electrolyte and fluid replacement therapy.

INFORMATION FOR PATIENT

The patient should be instructed to open and read directions and patient information sheet at least two (2) days in advance of the examination. Instruct the patient to use this product for bowel cleansing only as directed by a doctor, to discuss with the doctor the patient’s health and warnings about use of this product for bowel cleansing, to follow the special directions from the doctor exactly and to take only the dose the doctor has recommended.

The patient should be instructed to drink plenty of clear liquids before beginning the bowel preparation process; consider recommending the patient consume 36–48 fl. oz. of a carbohydrate-electrolyte solution in the six hours before the first dose is taken. During the bowel preparation process, the patient should be instructed to drink as much extra clear liquids as they can to replace the fluids lost during bowel movements: minimum 72 fl. oz. The patient should be instructed to drink as much liquid as possible after the procedure to help prevent dehydration.

WARNINGS FOR PATIENTS

DO NOT EXCEED RECOMMENDED DOSE UNLESS DIRECTED BY A PHYSICIAN. SERIOUS SIDE EFFECTS MAY OCCUR FROM EXCESS DOSAGE. IF THERE IS NO BOWEL MOVEMENT AFTER SIX HOURS, CONTACT A PHYSICIAN, AS ELECTROLYTE IMBALANCE AND CONSEQUENT SERIOUS SIDE EFFECTS COULD OCCUR.

During bowel preparation you will lose significant amounts of fluid. THIS IS NORMAL. It is very important that you replace this fluid to prevent dehydration. Early symptoms of dehydration include feeling thirsty, dizziness, urinating less often than normal, or vomiting. These symptoms may be signs of serious problems. Drink as much extra liquids as you can to help replace the fluids you are losing during bowel movements. Drinking large amounts of clear liquids also helps ensure that your bowel will be clean for the examination or procedure.

DO NOT TAKE MORE THAN 45 ML (1.5 FL. OZ.) PER DOSE. NEVER TAKE MORE THAN 1 BOTTLE AT ONE TIME.

Swallow Fleet® Bisacodyl Tablets whole; do not chew tablets unless directed by a physician. Do not take tablets within one hour after taking antacids, milk, or milk products.

DO NOT USE if you have congestive heart failure, if you have serious kidney problems, or in children under 18 years of age. Ask a doctor before use if you are under a doctor’s care for any medical condition, are on a low-salt diet or are pregnant or nursing a baby. Ask a doctor or pharmacist before use if you are taking any other prescription or nonprescription drugs. Ask a doctor before using any laxative if you have abdominal (belly) pain, nausea, or vomiting, have a change in your daily bowel movements that lasts more than 2 weeks, or have already used another laxative daily for constipation for more than 1 week. Stop using this product and consult a doctor if you have any rectal bleeding, do not have a bowel movement within 6 hours of taking this product or have any symptoms that your body is losing more fluids than you are drinking. This is called dehydration. Early symptoms of dehydration include feeling thirsty, dizziness, urinating less often than normal, or vomiting. These symptoms may be signs of serious problems.

Keep this and all drugs out of the reach of children. In case of accidental overdose or ingestion, seek professional assistance or contact a Poison Control Center right away.

Patient Information Sheet

Oral Sodium Phosphate Products for Bowel Cleansing

PLEASE REFER TO CARTON AND ENCLOSED INSTRUCTION SHEET FOR MORE INFORMATION.

IF ANY QUESTIONS, PLEASE CONTACT YOUR DOCTOR.

This is a summary of the most important information about oral sodium phosphate (OSP) bowel cleansing products. For details, talk to your healthcare professional.

What Are OSP Bowel Cleansing Products?

Bowel cleansing products are used to clean the stool out of your bowel before certain medical procedures, like colonoscopy.

What is the Most Serious Risk of Bowel Cleansing with Oral Sodium Phosphate Products?

A rare, but serious form of kidney failure has been associated with the use of oral sodium phosphate products.

Many of the reported cases involve patients with preexisting kidney problems or patients who are taking drugs that can affect kidney function (such as drugs for hypertension or arthritis) or that can affect hydration (fluid) status (such as diuretics-fluid pills). Kidney failure has also been reported in patients who are overdosed or contraindicated for the product, or who do not have a bowel movement after taking the product.

Who is at Most Risk for Kidney Failure with Use of OSP Bowel Cleansing Products?

You are at increased risk of developing kidney failure with the use of OSP bowel cleansing products if you have any of the following conditions:

- Heart Failure
- Previous kidney problems
- Are elderly
- Are taking certain medications that affect kidney function or hydration (fluid) status

What Are The Most Common Risks?

The following list includes the most common risks and side effects of OSP therapy. However, this list is not complete.

- **Dehydration**— tell your doctor if you have dizziness when you stand up or are urinating less often than normal. These are signs that you have lost too much fluid while using OSP. Tell your doctor if you are having trouble drinking liquids during your bowel cleansing or have been vomiting or feeling thirsty.
- Abdominal (belly) pain or bloating
- Nausea
- Vomiting
- Headache
- Dizziness

What Should I Tell My Healthcare Professional? Before you use OSP bowel cleansing products, tell your healthcare professional if you:

- Are on a low salt diet
- Use a diuretic (fluid pill), medicine for high blood pressure, or medicine for arthritis
- Use medicine for heart problems or seizures
- Have used a laxative for constipation in the past week
- Have a history of kidney problems
- Are pregnant or nursing a baby

Can Other Medicines Or Food Affect OSP Bowel Cleansing Products?

OSP bowel cleansing products and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how OSP bowel cleansing products work. Also, OSP bowel cleansing products may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

What Else Should I Know About OSP Bowel Cleansing Products?

Bowel cleansing products work by causing you to lose large amounts of fluid through your bowel movements. Frequent, loose and liquid bowel movements are expected. **It is very important that you replace this lost fluid to prevent dehydration.** Drinking large amounts of clear liquid (at least 72 fl. oz.) helps you replace the fluid you lose and helps clean your bowel for your procedure. Talk to your doctor about what you can drink to help lessen the chance of becoming dehydrated while using the OSP bowel cleansing products. **If you do not have a bowel movement within 6 hours of taking a dose of the product, call your doctor right away.**

DOSAGE AND ADMINISTRATION

SEE PATIENT INSTRUCTION SHEET FOR 18-, AND 24- HOUR PREPARATION SCHEDULE IN EACH KIT. The patient should open and read the enclosed directions, patient information sheet and labels at least 48 hours in advance of examination.

Phospho-soda® or any of the sodium phosphates-based bowel preparations should not be used for colon cleansing within seven (7) days of previous administration.

Additional patient instruction and information sheets are available by calling 1-866-255-6960 or by visiting www.fleetlabs.com

HOW SUPPLIED

See "Description" for contents of each kit.

Shipping Unit: 48 FLEET® Prep Kits per case.

For full prescribing information on specific products, see individual listings (FLEET® Phospho-soda®, FLEET® Bisacodyl Laxatives).

IS THIS PRODUCT OTC? Yes.

QUESTIONS? Call 1-866-255-6960 or visit www.fleetlabs.com.

