

FLEET® ENEMA 133 mL (Adult size), A SALINE LAXATIVE- ready-to-use squeeze bottle

(dibasic sodium phosphate/monobasic sodium phosphate) - C. B. Fleet Co., Inc.

FLEET® enemas are designed for quick, convenient administration by nurse, patient or caregiver according to instructions. Each is disposable after a single use.

(Prescribing Information excerpted from PDR.net)

COMPOSITION

FLEET® ENEMA: Each FLEET® Enema unit, with a 2-inch, pre-lubricated Comfortip®, contains 4.5 fl. oz. (133 mL) of enema solution in a ready-to-use squeeze bottle which is not made with natural rubber latex. Each enema unit delivers a dose of 118 mL, which contains 19 g monobasic sodium phosphate monohydrate and 7 g dibasic sodium phosphate heptahydrate. Each Fleet® Enema 118 mL delivered dose contains 4.4 grams sodium.

ELEMENTAL AND ELECTROLYTIC CONTENT

mEq	Phosphate (PO ₄) per mL	4.15
mEq	Sodium (Na) per mL	1.61
mg	Sodium (Na) per mL	37
mmole	Phosphorus (P) per mL	1.38

ACTION AND USES

FLEET® Enema, is useful as laxatives in the relief of occasional constipation and as part of a bowel cleansing regimen in preparing the colon for surgery, x-ray or endoscopic examination.

When used as directed, FLEET® Enema, provide thorough yet safe cleansing action and induce complete emptying of the left colon, usually within 1 to 5 minutes, without pain or spasm.

INFORMATION FOR PATIENT

WARNINGS

Using more than one enema in 24 hours can be harmful.

AFTER THE ENEMA SOLUTION IS ADMINISTERED, IF NO URGE TO EVACUATE IS FELT AFTER 5 MINUTES OF USING, TRY TO EMPTY BOWEL. CALL A DOCTOR PROMPTLY IF NO LIQUID COMES OUT OF THE RECTUM AFTER 30 MINUTES BECAUSE DEHYDRATION COULD OCCUR.

DO NOT USE ANY FLEET® ENEMA IN CHILDREN UNDER 2 YEARS OF AGE.

DO NOT ADMINISTER THE 4.5 FL. OZ. (133 mL) ADULT SIZE TO CHILDREN UNDER 12 YEARS OF AGE.

DO NOT ADMINISTER A FULL 2.25 FL. OZ. (66 mL) CHILDREN'S SIZE TO CHILDREN UNDER 5 YEARS OF AGE.

FOR CHILDREN 2 TO UNDER 5 YEARS, USE ONE-HALF BOTTLE OF 2.25 FL. OZ. (66 mL) CHILDREN'S SIZE. (SEE DOSAGE AND ADMINISTRATION).

IMPORTANT: FLEET® Enema (Adult size), FLEET® Enema EXTRA®, Fleet® Pedia-Lax® Enema and Fleet® Enema for Children ARE NOT INTENDED FOR ORAL CONSUMPTION in any dosage size.

When using any of these Fleet® enemas, patient may experience anal discomfort.

GENERAL LAXATIVE WARNINGS

Do not use without asking a doctor:

- for more than 3 days

- if you have (or your child has) kidney disease
- if you have (or your child has) heart problems
- if you are (or your child is) dehydrated

Ask a doctor before using this product if

- you are 55 years of age or older
- you are (or your child is) on a sodium-restricted diet

Ask a doctor before using any laxative if you have (or your child has)

- abdominal pain, nausea or vomiting
- a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more than 1 week

Stop using this product and consult a doctor if you have (or your child has)

- rectal bleeding
- no bowel movement or no liquid comes out of the rectum after 30 minutes
- symptoms of dehydration (feeling thirsty, dizziness, vomiting, urinating less often than normal)

These symptoms may indicate a serious condition.

Fleet enemas should be administered according to the instructions for use and handling. Stop use if resistance is encountered as forced administration of the enema may cause injury.

As with any drug, if you are pregnant or nursing a baby, seek the advice of a healthcare professional before using this product. As sodium phosphate may pass into the breast milk, it is advised that breast milk is expressed and discarded for at least 24 hours after receiving the Fleet® enema.

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

PROFESSIONAL USE INFORMATION

CONTRAINDICATIONS

Do not use in patients with

- Congestive heart failure
- Clinically significant impairment of renal function
- Known or suspected gastrointestinal obstruction
- Megacolon (congenital or acquired)
- Paralytic ileus
- Perforation
- Active inflammatory bowel disease
- Imperforate anus
- Dehydration
- Generally in all cases where absorption capacity is increased or elimination capacity is decreased
- Children under 2 years of age
- Hypersensitivity to active ingredients or to any of the excipients of the product

PRECAUTIONS

Use with caution in patients

- With impaired renal function
- Taking medications known to affect renal perfusion or function, or hydration status
- With pre-existing electrolyte disturbances or who are taking diuretics or other medications which may affect electrolyte levels
- Who are taking medications known to prolong the QT interval
- Ascites
- With a colostomy
- In children 2-11 years of age
- 55 years of age or older and under a doctor's care for any medical condition
- Who are pregnant or nursing a baby

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 and managed appropriately.

Fleet[®] Enema for Children should be used with caution in children of any age. Careful consideration of the use of enemas in children in general is recommended.

Careful consideration of the use of sodium phosphates enemas in the elderly with co-morbidities is also recommended. See PROFESSIONAL USE WARNINGS. In those cases where complications have been reported, elderly patients with co-morbidities are often involved.

Since FLEET[®] enemas contain sodium phosphates, in all patients there is a risk of elevated serum levels of sodium and phosphate and decreased levels of calcium and potassium, and consequently hypernatremia, hyperphosphatemia, hypocalcemia and hypokalemia may occur which could result in metabolic acidosis, tetany, renal failure, QT prolongation and/or, in more severe cases, multi-organ failure, cardiac arrhythmia/arrest and death. This is of particular concern in children with megacolon or any other condition where there is retention of enema solution, and in patients with co-morbidities, particularly gastrointestinal, renal and neurological disorders. If any patient develops vomiting and/or signs of dehydration, measure post-administration labs (phosphate, calcium, potassium, sodium, creatinine, GFR and BUN).

SINCE FLEET[®] BRAND ENEMAS ARE AVAILABLE IN ADULT, ADULT EXTRA, AND CHILDREN'S SIZES, PRESCRIBE CAREFULLY.

DRUG INTERACTIONS

NO OTHER SODIUM PHOSPHATES PREPARATIONS INCLUDING SODIUM PHOSPHATES ORAL SOLUTION OR TABLETS SHOULD BE GIVEN CONCOMITANTLY.

Electrolyte disturbances and hypovolemia from purgation may be exacerbated by inadequate oral fluid intake, nausea, vomiting, loss of appetite, or use of diuretics, angiotensin converting enzyme inhibitors (ACE-Is), angiotensin receptor blockers (ARBs), non-steroidal anti-inflammatory drugs (NSAIDs), and lithium or other medications that may affect electrolyte levels, and may result in metabolic acidosis, tetany, renal failure, QT prolongation and, in more severe cases, multi-organ failure, cardiac arrhythmia/arrest and death.

As hypernatremia is associated with lower lithium levels, concomitant use of Fleet[®] enemas and lithium therapy could lead to a fall in serum lithium levels with a lessening of effectiveness.

POSSIBLE SIDE EFFECTS

Hypersensitivity

Pruritis

Dehydration

Hyperphosphatemia

Hypocalcemia

Hypokalemia

Hypernatremia

Metabolic Acidosis

Nausea

Vomiting

Abdominal Pain

Abdominal Distension

Diarrhea

Gastrointestinal Pain

Chills

Blistering

Stinging

Anal Discomfort

Proctalgia

HYDRATION

Additional liquids by mouth are recommended.

Encourage patients to drink large amounts of clear liquids to prevent dehydration. Inadequate fluid intake when using any effective purgative may lead to excessive fluid loss, possibly producing dehydration and hypovolemia.

OVERDOSAGE OR RETENTION

Overdosage (more than one enema in a 24-hour period), no return of enema solution or failure to have a bowel movement within 30 minutes of enema use 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), QT prolongation and/or, in more severe cases, multi-organ failure, cardiac arrhythmia/arrest and death. The patient who has taken an overdose or who has retained the product for more than 30 minutes should be monitored carefully. If any patient develops vomiting and/or signs of dehydration, measure post-procedure labs (phosphate, calcium, potassium, sodium, creatinine, GFR and BUN). Treatment of electrolyte imbalance may require immediate medical intervention with appropriate electrolyte and fluid replacement therapy.

DOSAGE AND ADMINISTRATION

Dosage: FLEET® Enema (Adult size):

Use only 1 enema per 24 hours.

Do not use more unless directed by a doctor. See Warnings. Do not use if taking another sodium phosphates product.

Age	Daily Dose (per 24 hours)
adults and children 12 years and older	one bottle of FLEET® Enema (Adult size)
Children 2 to 11 years	use Fleet® Pedia-Lax® Enema or FLEET® Enema for Children
children under 2 years	DO NOT USE

How to use this enema:

- **REMOVE ORANGE PROTECTIVE SHIELD FROM ENEMA COMFORTIP® BEFORE INSERTING.**
- With steady pressure, gently insert enema tip into rectum with a slight side-to-side movement, with tip pointing toward navel. Insertion may be easier if person receiving enema bears down, as if having a bowel movement. This helps relax the muscles around the anus.
- Stop using if tip is hard to insert. Forcing the tip into the rectum can cause injury (especially if you have hemorrhoids). If enema tip causes rectal bleeding or pain, get immediate medical care.
- Squeeze bottle until nearly all liquid is gone. It is not necessary to empty the bottle completely, as it contains more liquid than needed.
- Remove Comfortip® from rectum and maintain position until urge to evacuate is strong (usually 1 to 5 minutes).

Positions for using this enema:

- Left-side position: Lie on left side with knee bent, and arms resting comfortably.
- Knee-chest position: Kneel, then lower head and chest forward until left side of face is resting on surface with left arm folded comfortably.

If no urge is felt after 5 minutes of using, try to empty bowel. Call a doctor promptly if no liquid comes out of the rectum after 30 minutes because dehydration could occur.

The diaphragm at base of nozzle prevents reflux and assures controlled flow of the enema solution. Fleet® Enema should be used at room temperature.

NO OTHER SODIUM PHOSPHATES PREPARATIONS INCLUDING SODIUM PHOSPHATES ORAL SOLUTION OR TABLETS SHOULD BE GIVEN CONCOMITANTLY.

FLEET® Enema (Adult size) should not be used in children under 12 years of age. In those cases where complications have been reported, infants and young children are often involved. Fleet® Pedia-Lax® Enema and FLEET® Enema for Children should be used with caution in children of any age. Careful consideration of the use of enemas in children in general is recommended.

Careful consideration of the use of sodium phosphates enemas in the elderly with co-morbidities is also recommended. See PROFESSIONAL USE WARNINGS. In those cases where complications have been reported, elderly patients with co-morbidities are often involved.

See DOSAGE AND ADMINISTRATION for dosing detail.

Proper and safe use of FLEET® Enemas also requires that the products be administered according to the Directions. Healthcare professionals should remember when administering the product to gently insert the enema into the rectum with the tip pointing toward the navel. Insertion may be made easier by having the patient bear down as if having a bowel movement. Care during insertion is necessary due to lack of sensory innervation of the rectum and due to possibility of bowel perforation. Once inserted, squeeze the bottle until nearly all the liquid is expelled. If resistance is encountered on insertion of the nozzle or in administering the solution, the procedure should be discontinued. Forcing the enema can result in perforation and/or abrasion of the rectum.

If an enema containing phosphate or sodium is not advised, consider using FLEET® Bisacodyl Enema.

HOW SUPPLIED

FLEET® Enema is supplied in a 4.5 fl. oz. (133-mL) ready-to-use squeeze bottle. NDC code: 0132020140 (single), 0132020142 (twin), 0132020145 (4-pack), 0132011946 (6-pack), Fleet® Enema EXTRA® is supplied in a 7.8 fl. oz. (230-mL) ready-to-use squeeze bottle. NDC code: 0132020110 Fleet® Pedia-Lax® Enema and Fleet® Enema for Children are supplied in a 2.25 fl. oz. (66 mL) ready-to-use squeeze bottle. NDC code: 0132020220

IS THIS PRODUCT OTC? Yes.

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