

FLEET® ENEMA, A SALINE LAXATIVE OTC
FLEET® ENEMA EXTRA®, A SALINE LAXATIVE
FLEET® PEDIA-LAX® ENEMA, A SALINE
LAXATIVE, FLEET® ENEMA FOR CHILDREN, A
SALINE LAXATIVE

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

COMPOSITION

FLEET® ENEMA: Each latex-free 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. 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.

FLEET® ENEMA EXTRA®: Each latex-free FLEET® Enema EXTRA® unit, with a 2 inch, pre-lubricated Comfortip®, contains 7.8 fl. oz. (230 mL) of enema solution in a ready-to-use squeeze bottle. Each enema unit delivers a dose of 197 mL, which contains 19 g monobasic sodium phosphate monohydrate and 7 g dibasic sodium phosphate heptahydrate. Each Fleet® Enema EXTRA® 197 mL delivered dose contains 4.4 grams sodium.

Fleet® Pedia-Lax® Enema and FLEET® ENEMA FOR CHILDREN: Each latex-free Fleet® Pedia-Lax® Enema and FLEET® Enema for Children unit, with a 2 inch, pre-lubricated Comfortip®, contains 2.25 fl. oz. (66 mL) of enema solution in a ready-to-use squeeze bottle. Each enema unit delivers a dose of 59 mL, which contains 9.5 g monobasic sodium phosphate monohydrate and 3.5 g dibasic sodium phosphate heptahydrate. Each Fleet® Enema for Children and Fleet® Pedia-Lax® Enema 59 mL delivered dose contains 2.2 grams sodium.

ELEMENTAL AND ELECTROLYTIC CONTENT (Fleet® Enema, Fleet® Pedia-Lax® Enema and Fleet® Enema for Children)

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

ELEMENTAL AND ELECTROLYTIC CONTENT (Fleet® Enema EXTRA®)

mEq Phosphate (PO ₄) per mL	2.484
mEq Sodium (Na) per mL	0.961
mg Sodium (Na) per mL	22.1
mmole Phosphorus (P) per mL	0.828

ACTION AND USES

FLEET® Enema, FLEET® Enema EXTRA® Fleet® Pedia-Lax® Enema and FLEET® Enema for Children are 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, FLEET® Enema EXTRA®, Fleet® Pedia-Lax® Enema and FLEET® Enema for Children 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, THE RETENTION TIME SHOULD NOT EXCEED 10 MINUTES. IF THE RETENTION TIME EXCEEDS 10 MINUTES OR THERE IS NO RETURN OF ENEMA SOLUTION, CONTACT A PHYSICIAN IMMEDIATELY, AS ELECTROLYTE DISTURBANCES AND CONSEQUENT SERIOUS SIDE EFFECTS COULD OCCUR.

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

DO NOT ADMINISTER THE 4.5 FL. OZ. ADULT SIZE OR THE 7.8 FL. OZ. EXTRA® SIZE TO CHILDREN UNDER 12 YEARS OF AGE.

DO NOT ADMINISTER A FULL 2.25 FL. OZ. 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. 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 laxative products when nausea, vomiting or abdominal pain is present unless directed by a physician. If you notice a sudden change in bowel habits that persists over a period of 2 weeks, consult a physician. 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. Stop using this product and consult a doctor if you have rectal bleeding following the use of this product as this may indicate a serious condition. Failure to have bowel movement within 30 minutes of using this product may also indicate a serious condition. Discontinue use and consult a physician. Laxative products should not be used longer than 1 week unless directed by a physician. 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. 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
- 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
- 65 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® 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.

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.

PDR® Physicians' Desk Reference®

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, retention time greater than 10 minutes 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 10 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.

DO dosage AND ADMINISTRATION

Dosage: FLEET® Enema (Adult size) and FLEET® Enema EXTRA®:

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

adults and children 12 years and older	one bottle
children 2 to 11 years	use Fleet® Pedia-Lax® Enema or FLEET® Enema for Children (See below)
children under 2 years	DO NOT USE

REMOVE ORANGE PROTECTIVE SHIELD FROM TIP BEFORE INSERTING.

Preferred position: Lie on left side with knee slightly bent and the right leg drawn up, or in knee-chest position. The diaphragm at base of tube prevents reflux and assures controlled flow of the enema solution. FLEET® Enema should be used at room temperature.

Dosage: Fleet® Pedia-Lax® Enema and FLEET® Enema for Children:

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

children 5 to 11 years	one bottle or as directed by a doctor
children 2 to under 5 years	one-half bottle (see below) or as directed by a doctor
children under 2 years	DO NOT USE

One-half bottle preparation: Unscrew cap and remove 2 Tablespoons of liquid with a measuring spoon. Replace cap and follow DIRECTIONS on back of carton.

REMOVE ORANGE PROTECTIVE SHIELD FROM TIP BEFORE INSERTING.

Preferred position: Lie on left side with knee slightly bent and the right leg drawn up, or in knee-chest position. The diaphragm at base of tube prevents reflux and assures controlled flow of the enema solution. Fleet® Pedia-Lax® Enema and FLEET® Enema for Children should be used at room temperature.

PROFESSIONAL DOSAGE AND ADMINISTRATION

Administration of more than one enema in 24 hours can be harmful. In those cases where complications have been reported, overdoses are often involved.

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

FLEET® Enema (Adult size) and FLEET® Enema EXTRA® 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. Fleet® Enema EXTRA® is supplied in a 7.8 fl. oz. (230-mL) ready-to-use squeeze bottle. Fleet® Pedia-Lax® Enema and Fleet® Enema for Children are supplied in a 2.25 fl. oz. (66 mL) ready-to-use squeeze bottle. **QUESTIONS?** Call 1-866-255-6960 or visit www.fleetlabs.com