

PRO-ENEMA SINGLE SALINE LAXATIVE- sodium phosphate, dibasic and sodium phosphate, monobasic, unspecified form enema
Propharma Medical Supplies

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Pro-Enema Single Saline Enema
Laxative

Drug Facts

<i>Active ingredients (in each 118mL delivered dose)</i>	<i>Purpose</i>
Dibasic Sodium Phosphate 7 g	Saline laxative
Monobasic Sodium Phosphate 19 g	Saline laxative

Use

Relieves occasional constipation

Warnings

Dosage warning

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

For rectal use only.

Ask a doctor before use if you

- already used a laxative for more than 1 week
- have kidney disease
- have heart problems
- are dehydrated
- are 55 years old or older
- are on a sodium-restricted diet

Ask a doctor before using any laxative if you have

- 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

When using this product

- **do not use more than directed. Serious side effects may occur from excess dosage**
- do not use for more than 3 days

Stop use and ask a doctor if

- you have bleeding
- the condition worsens or does not improve within 7 days
- you have no bowel movement within 30 minutes of enema use
- you have symptoms of dehydration (thirstiness, dizziness, vomiting, urinating less often than normal)

These symptoms may indicate a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away:

Directions

Single daily dosage (per 24 hours)

Do not use if taking another sodium phosphate product.

Do not use more unless directed by a doctor. See Warnings.

Adults and children 12 years old and older	1 bottle once daily
Children 2 to under 12 years old	1/2 bottle once daily
Children under 2 years	DO NOT USE

Other information

- **each 118 ml contains** 4.4 g sodium
- store at 15 to 30°C (59 to 86°F)
- additional liquids by mouth are recommended while using this product
- this product generally produces a bowel movement in 1 to 5 minutes
- **carton sealed for safety. Do not use if top or bottom flap of the carton is torn or missing**

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton

NDC 00000-000-00

*Compare To Fleet®

Ready-to-Use

Pro-Enema

Saline

Latex

Free

**For relief of
occasional
constipation**

1 Bottle

4.5 Fl Oz (133 mL)

Tamper Resistant
Do not use if top or bottom flap
of carton is torn or missing.

Ready-to-Use Pro-Enema

CARTON SEALED
FOR SAFETY. IF
SAFETY SEAL ON
THE TOP FLAP IS
BROKEN OR
MISSING, DO
NOT USE.

CAUTION:
REMOVE GREEN
PROTECTIVE
SHIELD FROM
ENEMA TIP
BEFORE
INSERTING.
PL32600B
V01

NDC 00000-000-00

Compare To Fleet

How To Use This Enema

- REMOVE GREEN PROTECTIVE SHIELD BEFORE INSERTING. Hold bottle upright grasping bottle cap with fingers. Grasp protective shield with other hand, and pull gently to remove.



- ADMINISTERING ENEMA:
 - 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. Doing so helps relax muscles around anus.
 - Do not force enema tip into rectum as this can cause injury.
 - Squeeze bottle until nearly all liquid is gone. It is not necessary to empty bottle completely, as it contains more liquid than needed.
 - Remove tip from rectum and stay in position until urge to evacuate is strong (usually 1 to 5 minutes).

- POSITIONING:
 - 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.



Bottle, cap, and shield are
LATEX FREE

Propharma
Medical Supplies

Manufactured for:
PROPHARMA MEDICAL SUPPLIES
Abu Dhabi, UAE
info@propharma.ae | www.propharma.ae



Ready-to-Use Pro-Enema Saline

Latex Free

For relief of occasional constipation



1 Bottle
4.5 Fl Oz (133 mL)

Ready-to-Use Pro-Enema

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داعي الاستخدام
يعالج الإمساك العارض
Use
Relieves occasional constipation

التحذيرات
استخدام أكثر من عبوة واحدة خلال 24 ساعة يمكن أن يسبب الأذى. للاستخدام الشرجي.

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Ready-to-Use Pro-Enema

Drug Facts (continued)

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Complete Enema In A Disposable Squeeze Bottle With Soft, Pre-Lubricated Tip.

Protective Shield Prevents Contamination
Comfortable, Lubricated Tip For Ease Of Insertion

One-Way Safety Valve Controls Flow And Prevents Reflux

Soft, Easy To Use Bottle



*This product is not manufactured or distributed by C.B.Fleet Company Inc., owner of the registered trademark Fleet®.



PRO-ENEMA SINGLE SALINE LAXATIVE

sodium phosphate, dibasic and sodium phosphate, monobasic, unspecified form enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71451-001
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium Phosphate, Dibasic (UNII: GR686LBA74) (PHOSPHATE ION - UNII: NK08V8K8HR, SODIUM CATION - UNII: LYR4M0NH37)	Sodium Phosphate, Dibasic	7 g in 118 mL
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII: NK08V8K8HR, SODIUM CATION - UNII: LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	19 g in 118 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71451-001-01	1 in 1 CARTON	06/06/2017	
1		133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	06/06/2017	

Labeler - Propharma Medical Supplies (558460257)

Revised: 6/2017

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