

TOPCARE ENEMA- dibasic sodium phosphate, monobasic sodium phosphate enema
Topco Associates LLC

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.

TOPCARE® ENEMA SALINE LAXATIVE
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
- this product generally produces bowel movement in 1 to 5 minutes

Warnings

For rectal use only.

Dosage warning

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

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
- 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: 800-222-1222.

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	Use Pediatric Enema
Children under 2 years	DO NOT USE

Other information

- **each 118 mL contains** 4.3 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 carton is torn or missing**

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton

TopCare®
health™

NDC 36800-002-02

COMPARE TO FLEET® ENEMA SALINE
ACTIVE INGREDIENTS*

Enema
Saline
Laxative

- For Relief of Occasional Constipation
- Soft, Flexible Tip
- Not Made with Natural Rubber Latex

- Ready-to-Use
Squeeze Bottle

1 BOTTLE

4.5 FL OZ (133 mL)

TopCare
health™

Enema Saline Laxative

PL 3165108
V03

TopCare
health™

NDC 31680-0-002-02

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ELK GROVE VILLAGE, IL 60007
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topcare@topco.com www.topcarebrand.com
MADE IN USA



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

*This product is not manufactured or distributed by C.B. Fleet Co., Inc., the distributor of Fleet® Enema Saline.

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Drug Facts (continued)

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Positions for using this enema
Left-side position

Lie on left side with knees 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.



How to use this enema

Remove protective shield from enema tip 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. 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).



TopCare
health™

Enema Saline Laxative

TAMPER EVIDENT CARTON SEALED FOR SAFETY. IF PRINTED SEAL ON BOTTOM OR TOP FLAP IS BROKEN OR MISSING, DO NOT USE.

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TOPCARE ENEMA

dibasic sodium phosphate, monobasic sodium phosphate enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-002
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	7 g in 118 mL
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (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 (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-002-02	1 in 1 CARTON	11/05/2009	
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-002-36	2 in 1 CARTON	11/05/2009	
2		133 mL in 1 BOTTLE; 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	11/05/2009	

Labeler - Topco Associates LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(36800-002)