# TOPCARE ENEMA- sodium phosphate, dibasic and sodium phosphate, monobasic 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.

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## **TopCare Enema Drug Facts**

# Active ingredients (in each 118 mL delivered dose)

Dibasic sodium phosphate 7 g

Monobasic sodium phosphate 19 g

# Purpose

Saline laxative

### Uses

relieves occasional constipation

## 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 have

- a sodium-restricted diet
- abdominal pain, nausea or vomiting
- kidney disease, heart problems, or are dehydrated
- noticed a sudden change in bowel habits that lasts over 2 weeks

## Ask a doctor or pharmacist before use if you are

taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

## 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 rectal bleeding
- you have no bowel movement after use of a laxative

These could be signs of 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. (1-800-222-1222)

## **Directions**

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

adults & children 12 years and over	one bottle once daily	
children 2 to under 12 years	½ bottle once daily	
children under 2 years	do not use	

## How to use this enema:

CAUTION: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.



## Positioning:

Left-side position: Lie on left side with knee bent and arms at rest.



## **Knee-chest position:**

Kneel, then lower head and chest forward until left side of face is resting on surface. Position arms comfortably.



## Administering enema:

- With steady pressure, gently insert enema with tip pointing toward navel.
- Squeeze bottle until recommended dose is expelled. nearly all liquid is gone. (It is not necessary to empty unit completely. Bottle contains more liquid than needed for effective use. A small amount of liquid will remain in bottle squeezing.)
- Remove tip from rectum.
- 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.
- Maintain position until urge to evacuate is strong (usually 1 to 5 minutes).
- If no urge is felt after minutes of using, try to empty bowel. Call a doctor promptly if no liquid comes of out the rectum after 30 minutes because dehydration could occur.

## Other information

- each 118 mL contains: sodium 4.3 g
- store at room temperature 20°-25°C (68°-77°F)
- this product generally produces bowel movement in 1 to 5 minutes

# **Inactive ingredients**

benzalkonium chloride, disodium EDTA, purified water

## Questions or comments?

1-888-423-0139

## **Principal Package Display**

NDC 36800-002-02

TopCare

LATEX FREE

**READY-TO-USE** 

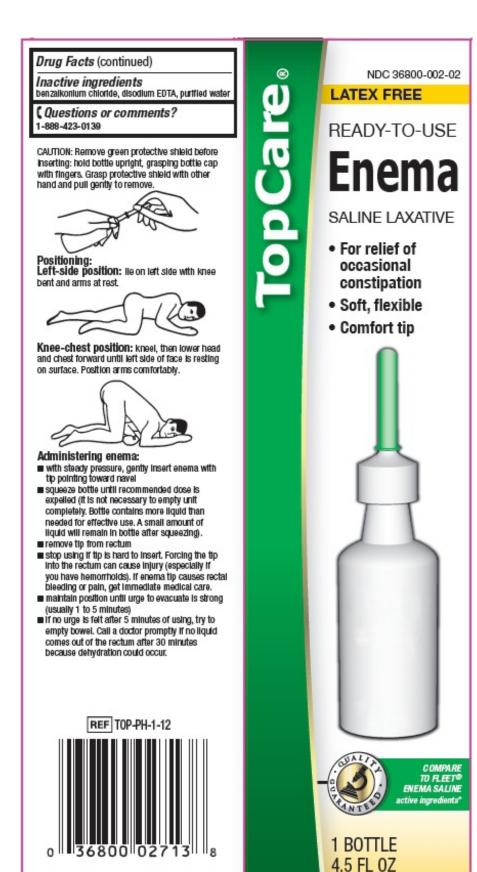
Enema

### SALINE LAXATIVE

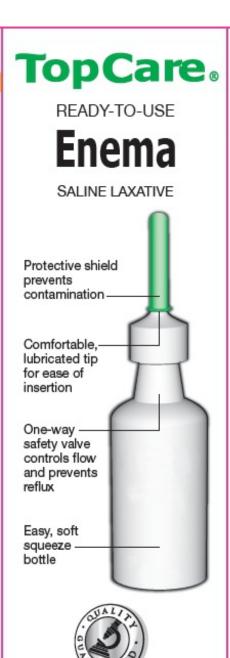
- For relief of occasional constipation
- Soft, flexible
- Comfort tip

COMPARE TO FLEET® ENEMA SALINE active ingredients

1 Bottle 4.5 FL OZ (133mL)



(133 mL)



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

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
1-888-423-0139
©TOPCO MDL1112
topcare@topco.com
Made in USA RA13MLW

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



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

## Drug Facts

Active ingredients (in each 118 mL

delivered dose) Dibasic sodium

Purpose

#### Uses

■ relieves occasional constipation

#### Warnings For rectal use only

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These could be signs of 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 Polson Control Center right away. (1-800-222-1222)

#### Directions

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

adults & children 12 years and over	one bottle once daily
children 2 to under 12 years	1/2 bottle once daily
children under 2 years	do not use

#### Other information

- each 118 mL contains: sodium 4.3 g
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- this product generally produces bowel movement in 1 to 5 minutes



#### TOPCARE ENEMA

dibasic sodium phosphate, monobasic sodium phosphate enema

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

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SO DIUM PHO SPHATE, DIBASIC (SODIUM CATION)	SODIUM PHOSPHATE, DIBASIC	7 g in 118 mL
SO DIUM PHO SPHATE, MO NO BASIC (SODIUM CATION)	SODIUM PHOSPHATE, MONOBASIC	19 g in 118 mL

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKO NIUM CHLO RIDE		
EDETATE DISO DIUM		
WATER		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-002-02	1 in 1 CARTON		
1		133 mL in 1 BOTTLE		
2	NDC:36800-002-36	2 in 1 CARTON		
2		133 mL in 1 BOTTLE		

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)

Revised: 12/2013 Topco Associates LLC