# SALINE LAXATIVE- sodium phosphate enema Kroger Company

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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## **Drug Facts**

## **Active ingredient**

(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 may be signs of a serious condition.

If pregnant or breastfeeding, 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	1/2 bottle once daily	
12 years	Discard unused portion	
children under 2 years	do not use	

## **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 (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 after 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 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.

#### Other Information

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

## **Inactive ingredients**

benzalkonium chloride, disodium EDTA, purified water

## Questions or comments?

1-800-633-5463

#### PRINCIPAL DISPLAY PANEL - 2 Bottle Carton

COMPARE TO the active ingredients of FLEET® ENEMA SALINE \*See side panel

NDC 30142-005-35

**TWIN** 

**PACK** 

Kroger<sub>®</sub>

**OUR PHARMACIST RECOMMENDED** 

**READY-TO-USE** 

Enema

SALINE LAXATIVE

Soft, Flexible Tip

For Relief of Occasional Constipation

- Lubricated Tip for Comfort Application
- Pre-Mixed
- Not Made with

Natural Rubber Latex

TAMPER EVIDENT SAFETY SEALED BOTTLES

FAST RELIEF

2 BOTTLES 4.5 FL OZ (133 ml) EACH TOTAL 9 FL OZ (266 mL) 400 VC31500B

IMPORTANT: READ ALL INSTRUCTIONS BEFORE USING THIS PRODUCT.



TAMPER RESISTANT DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.

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 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 enematip 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. 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 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). 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.

DISTRIBUTED
BY THE KROGER CO.
CINCINNATI, OHIO 45202
QUALITY GUARANTEE
800-632-6900
www.kroger.com





COMPARE TO the active ingredients of FLEET® ENEMA SALINE \*See side panel

NDC 30142-005-35





TWIN PACK

**READY-TO-USE** 

Enema

SALINE LAXATIVE

Soft, Flexible Tip

For Relief of Occasional Constipation

- Lubricated Tip for Comfort Application
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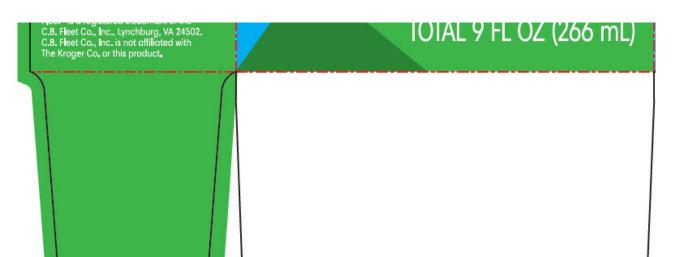
TAMPER EVIDENT SAFETY SEALED BOTTLES





**2** BOTTLES 4.5 FL OZ (133 mL) EACH

\*Fleet® is a registered trademark of the



IS BROKEN OR MISSING. DO NOT USE IF TOP FLAP



READY-TO-USE

# nema

## SALINE LAXATIVE

## Soft, Flexible Tip

For Relief of Occasional Constipation

- Lubricated Tip for **Comfort Application**
- Pre-Mixed
- Not Made with Natural Rubber Latex



Safety Seal for — added protection

Comfortable, lubricated tip for ease of insertion



nema

SALINE LAXATIVE

TAMPER EVIDENT: BOTTLE SEALED FOR SAFETY. DO NOT USE IF PRINTED SEAL AROUND NECK OF BOTTLE IS BROKEN OR MISSING.

## Drug Facts

Active Ingredients (in each 118 ml delivered dose)

Purpose

Dibasic Sodium Phosphate 7 g ... Monobasic Sodium Phosphate 19 g .. Saline laxative

- Use relieves occasional constipation this product generally produces bowel movement in 1 to 5 minutes

## Warnings

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

For rectal use only.

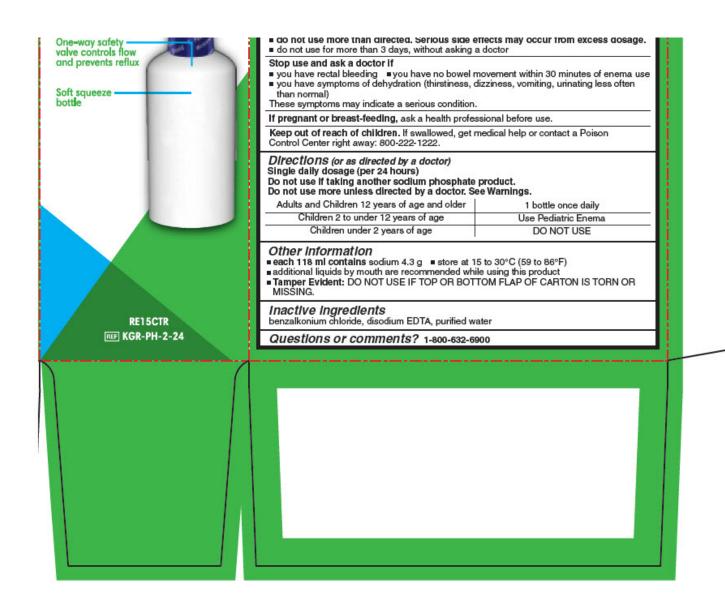
Do not use: • on children under 2 years of age

#### Ask a doctor before use if you:

- have already used a laxative for more than 3 days
   are 55 years of age or older
   have kidney disease, have heart problems, or are dehydrated
- are on a sodium-restricted diet
   have abdominal pain, nausea, or vomiting
- have a sudden change in bowel habits lasting more than 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:



## SALINE LAXATIVE

sodium phosphate enema

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-005
Route of Administration	RECTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM</b> (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	7 g in 118 mL	
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	19 g in 118 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)		

EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1 NDC:30142-005-35	2 in 1 BOX	08/31/2012	
1	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	08/31/2012	

## Labeler - Kroger Company (006999528)

Establishment			
Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(30142-005)

Revised: 1/2020 Kroger Company