

SALINE LAXATIVE- sodium phosphate enema

Safeway

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.

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 12 years	1/2 bottle once daily
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

Side and Principal Display Panel - box

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QUALITY & SATISFACTION GUARANTEED
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REF SFW-PH-2-12

S1872



RD 11014

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

NDC 21130-005-35

Compare to Fleet®
Enema Saline
active ingredients*

2

Units

Complete &
Ready-To-Use

Enema Saline Laxative



- For Relief of Occasional Constipation
- Comfortable Lubricated Tip
- Works in Minutes
- Pre-mixed
- Latex Free

Twin Pack

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

SAFEWAY  TM

NDC 21130-005-35

Compare to Fleet Enema Saline active ingredients*

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ENEMA

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SAFEWAY

Side and Back - box

TEP

Complete &
Ready-To-Use

Enema

Saline Laxative

- For Relief of Occasional Constipation
- Comfortable Lubricated Tip
- Works in Minutes
 - Pre-mixed
 - Latex Free

Protective shield prevents contamination

Comfortable, lubricated tip for ease of insertion

One-way safety valve controls flow and prevents reflux

Easy, soft squeeze bottle



Complete & Ready-To-Use

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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TEP

SALINE LAXATIVE

sodium phosphate enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-005
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, DIBASIC	7 g in 118 mL
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC	19 g in 118 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21130-005-35	2 in 1 BOX		
1		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	08/31/2012	

Labeler - Safeway (009137209)

Revised: 12/2013

Safeway