SALINE LAXATIVE- sodium phosphate enema American Sales 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.

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)

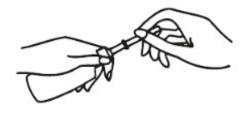
Directions

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

Side and Principal Display Panel - box



NDC 41520-005-11

Compare to the active ingredients in Fleet® Enema Saline

Care One

Ready-to-Use

ENEMA

Saline Laxative
Latex Free
For relief of occasional constipation
Single Pack
Soft, Flexible comfort tip
Tamper Evident Seals for Safety
4.5 FL OZ (133 ml)

Side and Back - box



SALINE LAXATIVE

sodium phosphate enema

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-005

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: 3980 JIH2SW) (PHOSPHATE ION - UNII: NK08 V8 K8 HR)	SODIUM PHOSPHATE, MONOBASIC	19 g in 118 mL			

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
WATER (UNII: 059QF0KO0R)			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41520-005-11	1 in 1 BOX			
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:41520-005-35	2 in 1 BOX			
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	08/31/2012				

Labeler - American Sales Company (809183973)

Revised: 6/2015 American Sales Company