GOOD NEIGHBOR PHARMACY- sodium phosphate enema enema AMERISOURCEBERGEN DRUG CORPORATION

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.

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 ½ bottle once daily Discard Unused portion		
children 2 to under 12 years			
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 until 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 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°C (68°-77°F)
- this product generally produces bowel movement in 1 to 5 minutes

Inactive ingredients

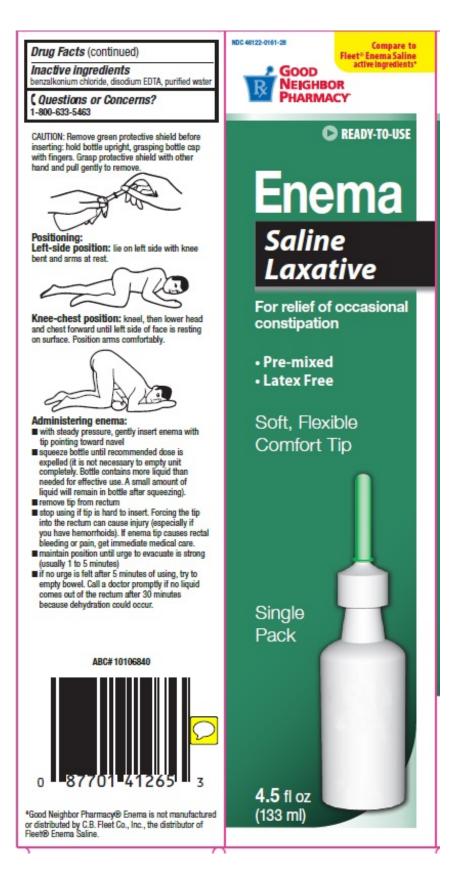
benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

1-800-633-5463

Principal Display Panel

Compare to Fleet® Enema Saline active ingredients Good Neighbor Pharmacy READY-TO-USE Enema Saline Laxative For Relief Of Occasional Constipation Pre-mixed Latex Free soft, flexible comfort tip 4.5 FL OZ (133ml)



Package Label - Back and Side Label with Drug Facts



GOOD NEIGHBOR PHARMACY

sodium phosphate enema enema

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

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NDC:46122-161

Active Ingredient/Active Moiety								
Ingredient Name				Basis of Strength		Strength		
SODIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)SODIUM DIBASIC				ODIUM PH IBASIC	OSPHATE,	7 g in 118 mL		
					SODIUM PHOSPHATE, MONOBASIC			
Inactive Ingredients								
Ingredient Name						Strength		
B	ENZALKO NIUM CI	ILORIDE (UNII: F5UM2KM3W7)						
E	DETATE DISODIUN	I (UNII: 7FLD9 1C86K)						
WATER (UNII: 059QF0KO0R)								
Packaging								
#	Item Code	Package Description	Marketing Sta	art Date	Marketing	End Date		
1	NDC:46122-161-28	1 in 1 CARTON						
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product						
2	NDC:46122-161-36	2 in 1 CARTON						
2		133 mL in 1 BOTTLE; Type 0: Not a Combination Product						
Marketing Information								
	Marketing Catego	ry Application Number or Monograph Citation	Marketing Sta	art Date	Marketing	, End Date		
OTC monograph not final part334		nal part334	0 3/0 1/20 13					

Labeler - AMERISO URCEBERGEN DRUG CORPORATION (007914906)

Revised: 6/2015

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