SALINE LAXATIVE- sodium phosphate enema Amerisource Bergen

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

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



Inactive ingredients benzalkonium chloride, disodium EDTA, purified wate **Compare to**

NDC 48122-500-11

Fleet[®] Enema Saline active ingredients*

GOOD

NEIGHBOR **PHARMACY**[®]

Ready-to-Use

Saline

constipation

 Pre-mixed Latex Free

Soft, Flexible

Comfort Tip

Laxative

For relief of occasional

:nema

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NDC 46122-500-11

Good Neighbor Pharmacy

Ready-to-Use

ENEMA

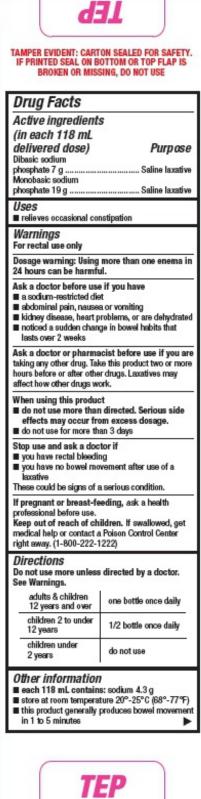
Saline Laxative

For relief of occasional constipation Pre-mixed Latex Free Soft, Flexible comfort tip Single Pack 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:46122-500

Active Ingredie	ent/Act	tive Moiety					
Ingredient Name			Basis	Basis of Strength		Strengtl	
SODIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74) (PHO SPHATE IO UNII:NK08V8K8HR)			PHATE ION -	SODIUM PH DIBASIC	SODIUM PHOSPHATE, DIBASIC		7 g in 118 mL
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR)			HOSPHATE ION -	SODIUM PHOSPHATE, MONOBASIC		Ε,	19 g in 118 mL
Inactive Ingree	dients						
		Ingredient Nam	ie			S	trength
BENZALKONIUM	CHLOR	IDE (UNII: F5UM2KM3W7)					
EDETATE DISO DI	/						
EDETATE DISODIC	UM (UNI	I: 7FLD91C86K)					
	,	,					
water (UNII: 0590 Packaging	QF0KO0	R)					
WATER (UNII: 0590 Packaging # Item Cod	QF0KO0 de	R) Package Description	Marketing	s Start Date	Mar	rketing	End Date
WATER (UNII: 0590 Packaging # Item Cod 1 NDC:46122-500-1	QF0KO0 de	R) Package Description 1 in 1 BOX	Marketing	s Start Date	Mar	rketing	End Date
WATER (UNII: 0590 Packaging # Item Cod 1 NDC:46122-500-1 1	QF0КО0 de 11	R) Package Description 1 in 1 BOX 133 mL in 1 BOTTLE	Marketing	s Start Date	Mar	rketing	End Date
WATER (UNII: 0590 P Kaging Item Cool NDC:46122-500-3 NDC:46122-500-3	QF0КО0 de 11	R) Package Description 1 in 1 BOX 133 mL in 1 BOTTLE 2 in 1 BOX	Marketing	s Start Date	Mar	rketing	End Date
WATER (UNII: 0590 Packaging # Item Cod 1 NDC:46122-500-3 1 NDC:46122-500-3	QF0КО0 de 11	R) Package Description 1 in 1 BOX 133 mL in 1 BOTTLE	Marketing	s Start Date	Mar	rketing	End Date
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Labeler - Amerisource Bergen (007914906)

Revised: 11/2012

Amerisource Bergen