GADAVYT ENEMA - dibasic sodium phosphate, monobasic sodium phosphate liquid Gadal Laboratories Inc

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 ingredients (in each 118 mL delivered dose)

Dibasic sodium phosphate 7 g...... Saline Laxative

Monobasic sodium phosphate 19 g...... 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 and 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	

Other information

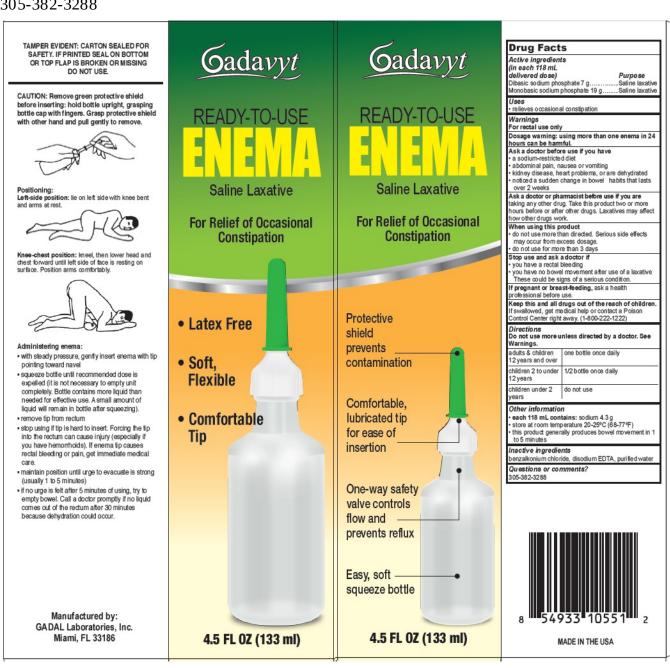
- each 118 mL contains: sodium 4.3 g
- store at room temperature 20-25 degrees C (68 -77 degrees F)
- this product generally produces bowel movement in 1 to 5 minutes

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

305-382-3288



GADAVYT ENEMA

dibasic sodium phosphate, monobasic sodium phosphate liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-104
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: 3980 JIH2SW) (PHOSPHATE ION - UNII: NK08 V8 K8 HR)	SODIUM PHOSPHATE, MONOBASIC	19 g in 118 mL	

Inactive Ingredients		
Ingredient Name	Strength	
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
WATER (UNII: 059QF0KO0R)		

]	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53113-104-45	133 mL in 1 BOTTLE, WITH APPLICATOR		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10 /0 1/20 12	

Labeler - Gadal Laboratories Inc (841305639)

Revised: 10/2012 Gadal Laboratories Inc