

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 59 mL delivered dose)

Dibasic sodium phosphate 3.5 g..... Saline Laxative

Monobasic sodium phosphate 9.5 g..... Saline Laxative

Uses

for relief of occasional constipation

Warnings

For rectal use only

Dosage warning: Using more than one enema in 24 hours can be harmful.

Ask a doctor before using this product if the child

- is on a sodium-restricted diet
- has kidney disease

Ask a doctor before using any laxative if the child has

- abdominal pain, nausea or vomiting
- a sudden change in bowel habits that lasting more than 2 weeks
- already used a laxative for more than 1 week

Stop use and ask a doctor if the child has

- rectal bleeding
- no bowel movement within 30 minutes of enema use
- symptoms of dehydration (feeling thirsty, dizziness, vomiting, urinating less often than normal)

These symptoms may indicate 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

Single Daily Dosage

Do not use more unless directed by a doctor. See Warnings

Do not use if child is taking another sodium phosphates product.

children 5 to 11	one bottle as directed by a doctor
children 2 to under 5 years	one-half bottle (see below)

One-half bottle preparation: Unscrew cap and remove 2 table spoons of liquid with a measuring spoon. Replace cap and follow directions below.

Other information

- each 59 mL delivered dose contains: sodium 2.2 g
- additional liquids by mouth are recommended while taking this product
- 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

Drug Facts (Continued)

Other information

- each 59-ml delivered dose contains: sodium 2.2g
- additional liquids by mouth are recommended while taking this product
- this product generally produces a bowel movement in 1-5 minutes.

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

305-362-3288

Protective shield prevents contamination

Comfortable, lubricated tip for ease of insertion

One-way safety valve controls flow and prevents reflux

Easy, soft squeeze bottle



Manufactured by:
GADAL Laboratories, Inc.
Miami, FL 33186

MADE IN THE USA

HOW TO USE THIS ENEMA:

- REMOVE ORANGE PROTECTIVE SHIELD FROM ENEMA TIP BEFORE INSERTING.



- With steady pressure, gently insert enema tip into rectum with a slight side-to-side movement, with tip pointing toward navel. Insertion may be easier if child receiving enema bears down, as if having a bowel movement. This helps relax the muscles around the anus.
- DO NOT FORCE THE ENEMA TIP INTO RECTUM AS THIS CAN CAUSE INJURY.
- Squeeze bottle until nearly all liquid is gone. It is not necessary to empty the bottle completely, as it contains more liquid than needed.
- Remove the tip from rectum and keep child in position until urge to evacuate is strong (usually 1 to 5 minutes). Do not allow child to retain enema solution for more than 10 minutes.

POSITIONS FOR USING THIS ENEMA:

- Left-side position:



Place child on left side with knees bent, and arms resting comfortably.

- Knee-chest position:



Have child kneel, then lower head and chest forward until left side of face is resting on surface with left arm folded comfortably.

Complete enema in a disposable squeeze bottle with soft, pre-lubricated tip

Tamper evident: carton sealed for safety. If top flap is broken or missing do not use.

Gadavyt

For Infants

READY-TO-USE

ENEMA

Saline Laxative

For Relief of Occasional Constipation

• Latex Free

• Soft, Flexible

• Comfortable Tip



2.25 FL OZ (66 mL)

Drug Facts

Active Ingredients
(in each 59 mL delivered dose)

	Purpose
Monobasic sodium phosphate 9.5g	Saline laxative
Dibasic sodium phosphate 3.5g	Saline laxative

Use

for relief of occasional constipation

Warnings

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- already used a laxative for more than 1 week

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- no bowel movement within 30 minutes of enema use
- symptoms of dehydration (feeling thirsty* dizziness* vomiting* urinating less often than normal)

These symptoms may indicate a serious condition

Keep out of reach of children.

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Directions

Single Daily Dosage

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Do not use if child is taking another sodium phosphates product.

children 5 to 11 years	1 bottle as directed by a doctor
children 2 to under 5 years	one-half bottle (see below)
children under 2 years	DO NOT USE

One-half bottle preparation: Unscrew cap and remove 2 table-spoons of liquid with a measuring spoon. Replace cap and follow direction below.



GADAVYT ENEMA

dibasic sodium phosphate, monobasic sodium phosphate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53113-105
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	3.5 g in 59 mL
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC	9.5 g in 59 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:53113-105-66	66 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	10/01/2012	

Labeler - Gadal Laboratories Inc (841305639)

Revised: 10/2012

Gadal Laboratories Inc