

**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.*

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**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

<p><b>TAMPER EVIDENT: CARTON SEALED FOR SAFETY. IF PRINTED SEAL ON BOTTOM OR TOP FLAP IS BROKEN OR MISSING DO NOT USE.</b></p> <p><b>CAUTION:</b> 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.</p>  <p><b>Positioning:</b>  <b>Left-side position:</b> lie on left side with knee bent and arms at rest.</p>  <p><b>Knee-chest position:</b> kneel, then lower head and chest forward until left side of face is resting on surface. Position arms comfortably.</p>  <p><b>Administering enema:</b></p> <ul style="list-style-type: none"> <li>• with steady pressure, gently insert enema with tip pointing toward navel</li> <li>• 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).</li> <li>• remove tip from rectum</li> <li>• 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.</li> <li>• maintain position until urge to evacuate is strong (usually 1 to 5 minutes)</li> <li>• 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.</li> </ul> <p><b>Manufactured by:</b>  <b>GADAL Laboratories, Inc.</b>  <b>Miami, FL 33186</b></p>	<p style="text-align: center;"><b>Gadavyt</b></p> <p style="text-align: center;">READY-TO-USE <b>ENEMA</b></p> <p style="text-align: center;">Saline Laxative</p> <p style="text-align: center;">For Relief of Occasional Constipation</p>  <p style="text-align: center;"><b>4.5 FL OZ (133 ml)</b></p> <ul style="list-style-type: none"> <li>• Latex Free</li> <li>• Soft, Flexible</li> <li>• Comfortable Tip</li> </ul>	<p style="text-align: center;"><b>Gadavyt</b></p> <p style="text-align: center;">READY-TO-USE <b>ENEMA</b></p> <p style="text-align: center;">Saline Laxative</p> <p style="text-align: center;">For Relief of Occasional Constipation</p>  <p style="text-align: center;"><b>4.5 FL OZ (133 ml)</b></p> <p>Protective shield prevents contamination</p> <p>Comfortable, lubricated tip for ease of insertion</p> <p>One-way safety valve controls flow and prevents reflux</p> <p>Easy, soft squeeze bottle</p>	<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each 118 mL delivered dose)</b></p> <table border="0"> <tr> <td>Dibasic sodium phosphate 7 g</td> <td>Saline laxative</td> </tr> <tr> <td>Monobasic sodium phosphate 19 g</td> <td>Saline laxative</td> </tr> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• relieves occasional constipation</li> </ul> <p><b>Warnings</b></p> <p><b>For rectal use only</b></p> <p><b>Dosage warning:</b> using more than one enema in 24 hours can be harmful.</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>• a sodium-restricted diet</li> <li>• abdominal pain, nausea or vomiting</li> <li>• kidney disease, heart problems, or are dehydrated</li> <li>• noticed a sudden change in bowel habits that lasts over 2 weeks</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking any other drug.</b> Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>• do not use more than directed. Serious side effects may occur from excess dosage.</li> <li>• do not use for more than 3 days</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• you have a rectal bleeding</li> <li>• you have no bowel movement after use of a laxative</li> </ul> <p>These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep this and all drugs out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)</p> <p><b>Directions</b></p> <p><b>Do not use more unless directed by a doctor. 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# GADAVYT ENEMA

dibasic sodium phosphate, monobasic sodium phosphate liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53113-104
<b>Route of Administration</b>	RECTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, DIBASIC	7 g in 118 mL
<b>SODIUM PHOSPHATE, MONOBASIC</b> (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC	19 g in 118 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>WATER</b> (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	10/01/2012	

**Labeler** - Gadal Laboratories Inc (841305639)

Revised: 10/2012

Gadal Laboratories Inc