

GENT-L-TIP- sodium phosphate enema

Chester Packaging

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 a period of 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.
- 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 12 years and over | one bottle once daily |
| children 2 to under 12 years | 1/2 bottle once daily Discard Unused Portion |
| 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 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 controlled room temperature
- this product generally produces bowel movement in 1 to 5 minutes

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

1-800-367-4477

Side and Principal Display Panel - box

Drug Facts (continued)

Inactive Ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

1-800-633-5463

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.



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Manufactured by
Chester Packaging, LLC.
Cincinnati, OH 45237
Made in USA. RD15CTR

NEP 101503

For product information call
1-800-255-8641



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NDC 12462-201-04

READY-TO-USE
gent-L-tip®
**ENEMA
SALINE LAXATIVE**

- Pre-Mixed
- For Relief of Occasional Constipation
- Lubricated Tip

Not made
with natural
rubber latex



4.5 FL OZ (133 ml)

REORDER NO. 101503

NDC 12462-201-04

READY-TO-USE

gent-L-tip

ENEMA

SALINE LAXATIVE

- Pre-Mixed
- For Relief of Occasional Constipation
- Lubricated tip

Latex Free

Chester Packaging

4.5 Fl OZ (133 ml)

REORDER NO. 101503

Side and Back - box

NDC 12462-201-04

READY-TO-USE gent-L-tip® ENEMA SALINE LAXATIVE

- Pre-Mixed
- For Relief of Occasional Constipation
- Lubricated Tip

Not made with natural rubber latex

Protective shield prevents contamination

Comfortable, lubricated tip for ease of insertion

One-way safety valve controls flow and prevents reflux

Soft squeeze bottle



4.5 FL OZ (133 ml)

TAMPER EVIDENT: CARTON SEALED FOR SAFETY. IF BOTTOM OR TOP FLAP IS BROKEN OR MISSING, DO NOT USE.

Drug Facts

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| | Purpose |
|---------------------------------|-----------------|
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If pregnant or breast-feeding, ask a health professional before use.

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Directions

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See Warnings.

| | |
|-------------------------------------|---|
| adults & children 12 years and over | one bottle once daily |
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| children under 2 years | do not use |

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

GENT-L-TIP

sodium phosphate enema

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:12462-201

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: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR) | SODIUM PHOSPHATE, MONOBASIC | 19 g in 118 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:12462-201-04 | 1 in 1 BOX | | |
| 1 | | 133 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:12462-201-91 | 45 in 1 CASE | | |
| 2 | | 133 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 01/03/2011 | 12/31/2017 |

Labeler - Chester Packaging (004237806)

Revised: 1/2016

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