

PURE AND GENTLE LAXATIVE- sodium phosphate enema
Medline Industries, LP

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.

014 Pure & Gentle Saline Enema Laxative

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
- this product generally produces bowel movement in 1 to 5 minutes

Warnings

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

For rectal use only.

Do not use

- on children under 2 years of age

Ask a doctor before use if you

- have already used a laxative for more than 3 days
- have kidney disease, have heart problems, or are dehydrated
- are 55 years of age or older
- are on a sodium-restricted diet
- have abdominal pain, nausea or vomiting
- have a sudden change in bowel habits lasting more than 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, without asking a doctor

Stop use and ask a doctor if

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

These symptoms may indicate 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

(or as directed by a doctor)

Single daily dosage (per 24 hours)

Do not use if taking another sodium phosphate product.

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

adults & children 12 years and over	1 bottle once daily
children 2 to under 12 years	Use Pediatric Enema
children under 2 years	DO NOT USE

CAUTION: Remove protective shield from enema tip before inserting.

Hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with other hand and pull gently to remove.



Positions for using this enema:

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 with left arm folded comfortably.



Administering enema:

- 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 person receiving enema bears down, as if having a bowel movement. Doing so helps relax muscles around anus.
- Do not force enema tip into 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.
- Squeeze bottle until nearly all liquid is gone. It is not necessary to empty unit completely, as it contains more liquid than needed.
- Remove tip from rectum and stay in 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 15-30°C (59-86°F)
- additional liquids by mouth are recommended while using this product
- **Tamper Evident:** DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

866-323-0107

Manufacturing Information

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Made in USA

www.medline.com

1-800-MEDLINE (633-5463)

REF: CUR095005

V1 RD22NPX

Package Label



NDC 53329-014-11

**Pure
&
Gentle.**

Saline

Enema

Laxative



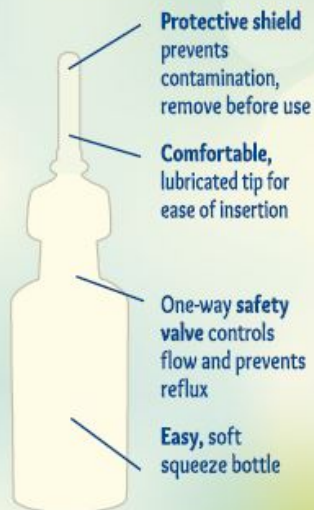
**Comfortable
Lubricated Tip**

Easy to Insert
Ready-to-Use
Not made with
Natural Rubber Latex

1 - 4.5 fl oz (133 mL)



Saline Enema



www.medline.com ©2022
Pure & Gentle is a registered trademark of Medline Industries, LP. Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA. Made in USA. 1-800-MEDLINE V1 RD22NPX

REF CUR095005



NDC 53329-014-11



Saline Enema Laxative



Easy to Insert
Ready-to-Use
Not made with
Natural Rubber Latex

1 - 4.5 fl oz (133 mL)

TAMPER RESISTANT: DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.

CAUTION: Remove protective shield before inserting.
Hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with other hand and pull gently to remove.



Positions for using this enema:
Left-side position:
Lie on left side with knees bent and arms resting comfortably.



Knee-chest position:
Kneel, then lower head and chest forward until left side of face is resting on surface with left arm folded comfortably.



Administering enema:

- 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 person receiving enema bears down, as if having a bowel movement. Doing so helps relax muscles around anus.
- Do not force enema tip into 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.
- Squeeze bottle until nearly all liquid is gone. It is not necessary to empty bottle completely, as it contains more liquid than needed.
- Remove tip from rectum and stay in 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.

Drug Facts

Active ingredients	Purpose
<i>(in each 118 mL delivered dose)</i>	
Dibasic Sodium Phosphate 7 g	Saline laxative
Monobasic Sodium Phosphate 19 g	Saline laxative

Use ■ relieves occasional constipation
■ this product generally produces bowel movement in 1 to 5 minutes

Warnings

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

For rectal use only.

Do not use ■ on children under 2 years of age

Ask a doctor before use if you

■ have already used a laxative for more than 3 days ■ have kidney disease, have heart problems, or are dehydrated ■ are 55 years of age or older ■ are on a sodium-restricted diet ■ have abdominal pain, nausea, or vomiting ■ have a sudden change in bowel habits lasting more than 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, without asking a doctor

Stop use and ask a doctor if

■ you have rectal bleeding ■ you have no bowel movement within 30 minutes of enema use ■ you have symptoms of dehydration (thirstiness, 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: 800-222-1222.

Directions (or as directed by a doctor)

Single daily dosage (per 24 hours)
Do not use if taking another sodium phosphate product.
Do not use more unless directed by a doctor. See Warnings.

Adults and children 12 years old and older	1 bottle once daily
Children 2 to under 12 years old	Use Pediatric Enema
Children under 2 years	DO NOT USE

Other information ■ each 118 mL contains sodium 4.3 g ■ store at 15 to 30°C (59 to 86°F) ■ additional liquids by mouth are recommended while using this product
■ **Tamper Evident: DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.**

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

1-866-323-0107

PURE AND GENTLE LAXATIVE

sodium phosphate enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-014
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: 3980JH2SW) (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:53329-014-11	1 in 1 BOX	11/10/2017	
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:53329-014-58	24 in 1 CASE	11/03/2017	
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	04/09/2014	

Labeler - Medline Industries, LP (025460908)

Revised: 9/2022

Medline Industries, LP