

CVS PHARMACY- saline laxative enema

CVS Pharmacy

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.

CVS PHARMACY saline laxative enema

Drug Facts

Active ingredients (in each 59 mL delivered dose)	Purpose
Dibasic Sodium Phosphate 3.5g	Saline laxative
Monobasic Sodium Phosphate 9.5g	Saline laxative

Use

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

Warnings

For rectal use only.

Dosage warning

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

Ask a doctor or pharmacist before using if the child

- 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
- 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 the child

- has rectal bleeding
- has no bowel movement within 30 minutes of enema use
- has symptoms of dehydration (thirstiness, dizziness, vomiting, urinating less often than normal)
These symptoms may indicate a serious condition.

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.

children 2 to 11 years	1 bottle once daily
children under 2 years	ask a doctor

Other information

- **each 59 mL contains: sodium 2.2g**
- 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?

866-323-0107 or www.natureplex.com

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

PRINCIPAL DISPLAY PANEL - 66 mL Bottle Carton

CVS

Health™

Compare to the active ingredients in Fleet®

Pedia-Lax Enema*

NDC 59779-969-40

Children's

Ready-to-Use

Enema

SALINE LAXATIVE

- Pre-mixed
- For relief of occasional constipation
- Lubricated tip

AGES

2-11

2.25 FL OZ (66 mL)



Children's Ready-to-Use Enema

SALINE LAXATIVE

PL31106B
V04

Positions for using this enema

Left-side position: have the child lie on left side with knees bent and arms resting comfortably.



Knee-chest position: have the child kneel, then lower the child's head and chest forward until left side of face is resting on surface with left arm folded comfortably.



How to use this enema

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.



Administering enema:

- With steady pressure, gently insert enema tip into child's 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. 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 the child has 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 have child stay in position until urge to evacuate is strong (usually 1 to 5 minutes). If no urge is felt after 5 minutes of using, have child try to empty bowel. Call a doctor promptly if no liquid comes out of the rectum after 30



Compare to the active ingredients in Fleet® Pedia-Lax Enema™

NDC 59779-969-40

Children's Ready-to-Use Enema

SALINE LAXATIVE

- Pre-mixed
- For relief of occasional constipation
- Lubricated tip

AGES
2-11

minutes because denaturation could occur.

*CVS Health™ Children's Ready-to-Use Enema is not manufactured or distributed by C.B. Fleet Co., Inc., the distributor of Fleet® Pedia-Lax Enema.

Distributed by: CVS Pharmacy, Inc.
One CVS Drive, Woonsocket, RI 02895

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Made in the U.S.A. RE14CTR
V-32922



CVS Quality
Money Back Guarantee

REF CVS977149N

REF #977149



0 50428 35432 2

2.25 FL OZ (66 mL)

LOT:

EXP:

CVS
Health

Drug Facts

Active ingredients	Purpose
<i>(in each 59 mL delivered dose)</i>	

Children's Ready-to-Use Enema

SALINE LAXATIVE

- Pre-mixed
- For relief of occasional constipation
- Lubricated tip

Protective shield prevents contamination

Safety seal for added protection

Comfortable, lubricated tip for ease of insertion

One-way safety valve controls flow and prevents reflux

Soft squeeze bottle



NOT MADE WITH NATURAL RUBBER LATEX

**TAMPER EVIDENT:
IF PRINTED SEAL AROUND
NECK OF BOTTLE IS BROKEN
OR MISSING, DO NOT USE.**

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Stop use and ask a doctor if the child ■ has rectal bleeding ■ has no bowel movement within 30 minutes of enema use ■ has symptoms of dehydration (thirstiness, dizziness, vomiting, urinating less often than normal) These symptoms may indicate a serious condition.

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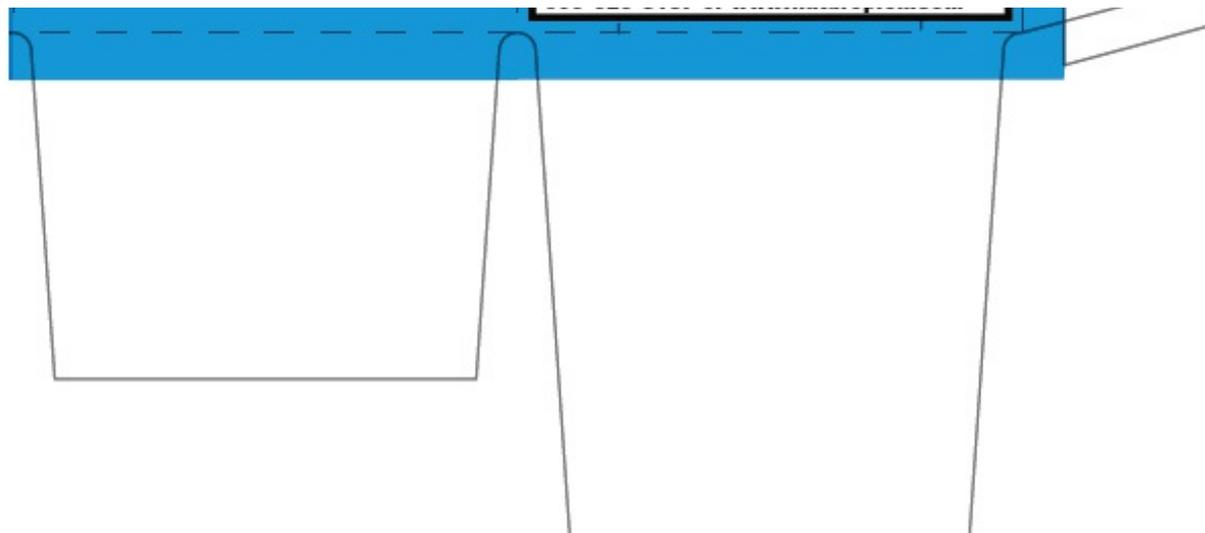
Other information ■ each 59 mL contains: sodium 2.2g ■ store at 15 to 30°C (59 to 86°F) ■ additional liquids by mouth are recommended while using this product ■ **Tamper Evident: DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.**

Inactive ingredients

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Questions or comments?

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CVS PHARMACY

saline laxative enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-969
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) (PHOSPHATE ION - UNII: NK08V8K8HR, SODIUM CATION - UNII: LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	3.5 g in 59 mL
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII: NK08V8K8HR, SODIUM CATION - UNII: LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	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:59779-969-40	1 in 1 CARTON	05/20/2014	
1		59 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

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(59779-969)

Revised: 12/2017

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