

SALINE LAXATIVE- sodium phosphate enema

Walgreen Company

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.

WALGREENS READY TO USE ENEMA LAXATIVE

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

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 the child

- has already used a laxative for more than 3 days
- has kidney disease, have heart problems, or is dehydrated
- is on a sodium-restricted diet
- has abdominal pain, nausea, or vomiting
- has a sudden change in bowel habits lasting more than 2 weeks

Ask a doctor or pharmacist before use if the child is 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 under 12 years of age	Use 1 bottle once daily
children under 2 years of age	DO NOT USE

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?

1-866-323-0107

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015

PRINCIPAL DISPLAY PANEL - 67 mL Bottle Box

Walgreens

Compare to Fleet®
Pedia-Lax® Enema
active ingredients††

NDC 0363-0005-40

READY-TO-USE
Pediatric
Enema
SALINE LAXATIVE

SALINE LAXATIVE
PRE-MIXED

- For relief of occasional constipation
- Comfortable, lubricated tip
- Not made with natural rubber latex

NOT ACTUAL SIZE

2.25 FL OZ (67 mL)

CAUTION:
REMOVE GREEN
PROTECTIVE
SHIELD FROM
ENEMA TIP
BEFORE
INSERTING
PL31259B
W08

Walgreens
READY-TO-USE
**Pediatric
Enema**
SALINE LAXATIVE

CARTON SEALED
FOR SAFETY. IF
SAFETY SEAL ON
THE TOP FLAP IS
BROKEN OR
MISSING, DO
NOT USE.

Walgreens Ready-to-Use Pediatric Enema With Saline Laxative

Comfortable, lubricated tip for ease of insertion
Protective shield prevents contamination
One-way safety valve controls flow and prevents reflux
Safety seal for added protection



Easy, soft-squeeze bottle



Walgreens
Compare to Fleet®
Pedia-Lax® Enema
active ingredients!
NDC 0363-0005-40

READY-TO-USE
**Pediatric
Enema**
SALINE LAXATIVE

TAMPER EVIDENT: CARTON AND BOTTLE SEALED FOR SAFETY. DO NOT USE IF PRINTED SEAL ON CARTON OR PRINTED SEAL AROUND NECK OF BOTTLE IS BROKEN OR MISSING.

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 the 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.

How to Use this Enema:
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.



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.



SALINE LAXATIVE
PRE-MIXED

- For relief of occasional constipation
- Comfortable, lubricated tip
- Not made with natural rubber latex



NOT ACTUAL SIZE

2.25 FL OZ (67 mL)

[†]Walgreens Pharmacist Survey
^{††}This product is not manufactured or distributed by C.B. Fleet Company, Inc., owner of the registered trademark Fleet® Pedia-Lax®.

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
walgreens.com ©2018 Walgreen Co.

MADE IN U.S.A. OF U.S. AND
IMPORTED COMPONENTS
ITEM 941344 W10094-0000-L



Drug Facts

Active ingredients Purpose
(in each 59 ml delivered dose)
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
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 the child
■ has already used a laxative for more than 3 days ■ has kidney disease, have heart problems, or is dehydrated ■ is on a sodium-restricted diet ■ has abdominal pain, nausea, or vomiting ■ has a sudden change in bowel habits lasting more than 2 weeks

Ask a doctor or pharmacist before use if the child is 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 under 12 years of age	Use 1 bottle once daily
children under 2 years of age	DO NOT USE

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?
1-866-323-0107



ORG0418-F
REV- 1220

SALINE LAXATIVE

sodium phosphate enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0005
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 PHOSPHATE, DIBASIC, UNSPECIFIED FORM	7 g in 118 mL
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII: NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	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:0363-0005-37	1 in 1 BOX	03/11/2016	
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0363-0005-38	3 in 1 BOX	03/11/2016	
2		133 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
3	NDC:0363-0005-39	6 in 1 BOX	03/11/2016	
3		133 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
4	NDC:0363-0005-11	1 in 1 BOX	08/31/2012	03/11/2016
4		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0363-0005-36	3 in 1 BOX	08/31/2012	03/11/2016
5		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0363-0005-20	6 in 1 BOX	08/31/2012	03/11/2016
		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		

6		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0363-0005-40	24 in 1 BOX	08/31/2012	03/11/2016
7		66.5 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	08/31/2012	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(0363-0005)

Revised: 3/2021

Walgreen Company