

PEDIA-LAX- sodium phosphate, dibasic and sodium phosphate, monobasic enema

C.B. Fleet Company, 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.

Pedia-Lax Enema Saline Laxative 0132-0202

PEDIA-LAX sodium phosphates Saline Enema

C.B. Fleet Company, Inc.

Drug Facts

Active Ingredients

(in each 59-mL delivered dose)

Monobasic Sodium Phosphate 9.5 g.....

Dibasic Sodium Phosphate 3.5 g.....

Purpose

Saline laxative

Saline laxative

Use

for relief of occasional constipation.

Warnings

For rectal use only.

Dosage Warning:

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

Do not use without asking a doctor:

- for more than 3 days
- if your child has a kidney disease
- if your child has heart problems
- if your child is dehydrated

Ask a doctor before using this product if the child

- is on a sodium-restricted diet

Ask a doctor before using any laxative if your child has

- abdominal pain, nausea, or vomiting
- a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more than 1 week

Stop use and ask a doctor if your child has

- rectal bleeding
- no bowel movement or no liquid comes out of the child’s rectum after 30 minutes
- symptoms of dehydration [feeling thirsty, dizziness, vomiting, urinating less often than normal]

These symptoms may indicate a serious condition.

Keep out of reach of children to prevent accidental ingestion.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Single Daily Dosage (per 24 hours)

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

Do not use if child is taking another sodium phosphates product.

Age	Dose
children 5 to 11 years	1 bottle per day or as directed by doctor
children 2 to under 5 years	one-half bottle per day (see below)
children under 2 years	DO NOT USE

One-half bottle preparation:

Unscrew cap and remove 2 tablespoons of liquid with a measuring spoon. Replace cap and follow “How to use this enema” directions.

Other information

- **each 59-mL delivered dose contains:** sodium 2.2g
- **additional liquids by mouth are recommended while taking this product**
- this product usually produces a bowel movement in 1-5 minutes
- **BOTTLE SEALED FOR SAFETY. IF BOTTLE WRAPPER WITH FLEET® EMBLEM IS TORN, DAMAGED, OR MISSING, DO NOT USE**
- **for complete professional use, warnings and precautions, consult the Reference Safety Information on our website**

Inactive Ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions?

1-866-255-6960

www.pedia-lax.com

Fleet® Enemas are LATEX-FREE

PRINCIPAL DISPLAY PANEL

Pedia-Lax
Sodium Phosphates
Saline Enema
2.25 fl oz (66 mL)



PEDIA-LAX

sodium phosphate, dibasic and sodium phosphate, monobasic enema

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0132-0202

Route of Administration RECTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	3.5 g in 66 mL
sodium phosphate, monobasic (UNII: 3980JH2SW) (SODIUM CATION - UNII:LYR4M0NH37, PHOSPHATE ION - UNII:NK08V8K8HR)	sodium phosphate, monobasic	9.5 g in 66 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0202-20	66 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/10/2002	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/10/2002	

Labeler - C.B. Fleet Company, Inc. (003119054)

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