

REFLIEF SALINE LAXATIVE PEDIATRIC READY TO USE- sodium phosphate, dibasic, unspecified form and sodium phosphate, monobasic, unspecified form enema

Leosons International

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.

Relief Pediatric Enema (NaturePlex)

Drug Facts

Drug Facts

Active ingredients & Purpose

<i>Active ingredients (in each 59 ml delivered dose)</i>	<i>Purpose</i>
Dibasic Sodium Phosphate 3.5g.....	Saline laxative
Monobasic Sodium Phosphate 9.5g.....	Saline laxative

Uses

- 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.

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 are 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 2.2g sodium**
- 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?

Call toll-free at **+1-855-452-9500** or email **info@Leosonsintl.com**

Distributed by:

Leosons

10 Maryland Avenue
Albany, New York 12205

PRINCIPAL DISPLAY PANEL

NDC 69626-0085-7

RELIEF™
SALINE LAXATIVE

Pediatric
Ready-to-Use

ENEMA

For relief of occasional constipation

- Pre-Mixed
- Not Made With Natural Rubber Latex

Ages 2-11

Lubricated Tip
2.25 FL OZ (67 mL)





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 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 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.

Bottle, cap and shield are NOT MADE WITH NATURAL RUBBER LATEX

Allergic reaction to materials containing Latex is a growing and serious medical problem.

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Leosons
10 Maryland Avenue
Albany, New York 12205



With Natural Rubber Latex
Ages 2-11



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RUBBER LATEX
Ages 2-11

Complete Enema in a Disposable Squeeze Bottle with Soft, Pre-Lubricated Tip

Protective Shield Prevents Contamination

Comfortable, Lubricated Tip For Ease of Insertion

One-Way Safety Valve Controls Flow and Prevents Reflux

Soft, Easy-to-Use Bottle



REFLIEF SALINE LAXATIVE PEDIATRIC READY TO USE

sodium phosphate, dibasic, unspecified form and sodium phosphate, monobasic, unspecified form enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69626-0085
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
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BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69626-0085-7	1 in 1 CARTON	10/01/2019	
1		67 mL in 1 BOTTLE, PLASTIC; 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	10/01/2019	

Labeler - Leosons International (148605470)

Revised: 12/2022

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