

PEDIATRIC SALINE LAXATIVE- sodium phosphate, monobasic, unspecified form and sodium phosphate, dibasic enema
Natureplex, LLC

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.

**Pediatric
Saline Laxative**

Drug Facts

<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

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.

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 old	1 bottle once daily
children under 2 years	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?

866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 67 mL Bottle Carton

Natureplex™

pediatric
ages 2-11

NDC 67234-042-01

ENEMA

*Compare
To
Fleet®

saline laxative

- Not Made with Natural Rubber Latex
- Pre-mixed
- For relief of occasional constipation
- Pre-lubricated tip

Bottle
2.25 Fl Oz
(67 mL)

3110B
V04

CAUTION:
REMOVE BLUE
PROTECTIVE
SHIELD FROM
ENEMA TIP
BEFORE
INSERTING

Tamper Resistant
Do not use if top or bottom flap
of carton is torn or missing.

Natureplex
pediatric
E N E M A

ages 2-11

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

Natureplex

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 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 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.

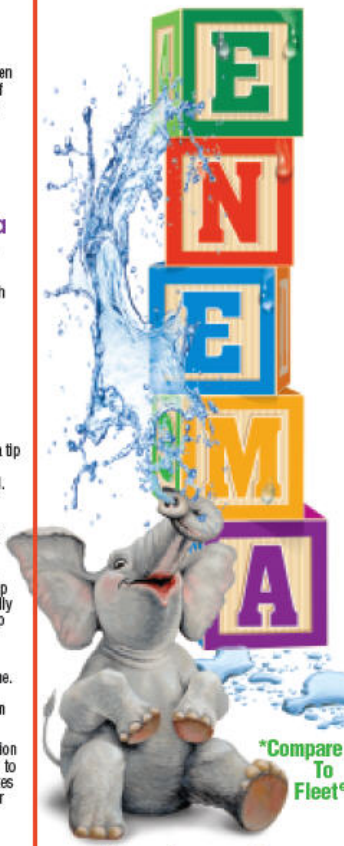
Natureplex

OLIVE BRANCH, MS 38654



Natureplex
pediatric
ages 2-11

NDC 67234-042-01

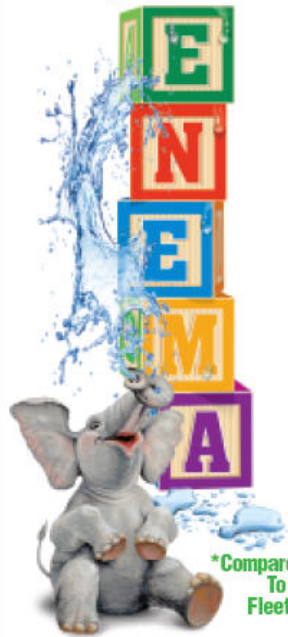


*Compare To Fleet®

saline laxative

- Not Made with Natural Rubber Latex
 - Pre-mixed
 - For relief of occasional constipation
 - Pre-lubricated tip
- 1** Bottle
2.25 Fl Oz (67 mL)

Natureplex
pediatric
ages 2-11



*Compare To Fleet®

Complete Enema In A Disposable Squeeze Bottle With Soft, Pre-Lubricated Tip.

Protective Shield Prevents Contamination

Comfortable, Pre-lubricated Tip For Ease Of Insertion

One-Way Safety Valve Controls Flow And Prevents Reflux

Soft, Easy To Use Bottle



* This product is not manufactured or distributed by C.B. Fleet Company Inc., owner of the registered trademark Fleet®.

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

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 old	1 bottle once daily
children under 2 years	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?

866-323-0107 or www.natureplex.com

PEDIATRIC SALINE LAXATIVE

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-042
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	3.5 g in 59 mL
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	9.5 g in 59 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:67234-042-01	1 in 1 CARTON	08/31/2012	
1		67 mL in 1 BOTTLE, WITH APPLICATOR; 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 - Natureplex, LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(67234-042)