

NATUREPLEX ENEMA- (saline) 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.

SALINE ENEMA

LAXATIVE

Drug Facts

Active ingredients (in each 118mL delivered dose)	Purpose
Dibasic Sodium Phosphate 7 g	Saline laxative
Monobasic Sodium Phosphate 19 g	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 you

- 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

- you have rectal bleeding
- you have no bowel movement within 30 minutes of enema use
- you have symptoms of dehydration (thirstiness, dizziness, vomiting, urinating less often than normal)

These symptoms may indicate a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

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.

Adults and children 12 years of age and older	1 bottle once daily
Children 2 to under 12 years of age	Use Pediatric Enema
Children under 2 years of age	DO NOT USE

Other information

- **each 118 ml contains** 4.3 g 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 - 133 mL Bottle Carton

NDC 67234-020-01

*Compare To Fleet®

Natureplex™

READY TO USE

Enema Saline

Not Made

with Natural Rubber Latex

For Relief Of Occasional Constipation

Soft, Easy To Use Bottle (133 mL)

NATUREPLEX ENEMA

(saline) enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67234-020
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	19 g in 133 mL
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	7 g in 133 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:67234-020-01	1 in 1 CARTON	06/01/2010	
1		133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		
2	NDC:67234-020-02	2 in 1 CARTON	06/01/2010	
2		133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		
3	NDC:67234-020-03	3 in 1 CARTON	06/01/2010	
3		133 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	06/01/2010	

Labeler - Natureplex, LLC (062808196)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex, LLC		062808196	manufacture(67234-020)