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
- vou 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®

 $Nature plex^{\text{\tiny TM}}$

READY TO USE

Enema

Saline

Not Made

with

Natural

Rubber

Latex

For

Relief Of

Occasional

Constipation

Soft, Easy To Use Bottle

1 Bottle 4.5 Fl Oz (133 mL)

Tamper Resistant Do not use it top or bottom flap of carton is tom or missing.

READY TO USE

3015B V20 MOVE GREEN
PROTECTIVE
PROTECTIVE
HELD FROM
ENEMATIP
BEFORE
INSERTING.

Positions for using this enema

Left-side position: Lie on left side with knees bent and arms resting comfortably.



Knee-chest position: 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

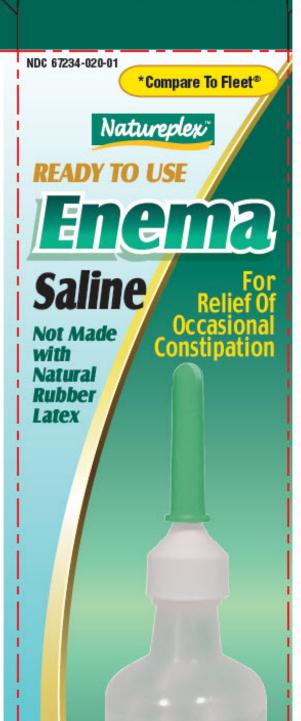
 Remove protective shield from enema tip before inserting.

Hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with other hand and pull gently to remove.

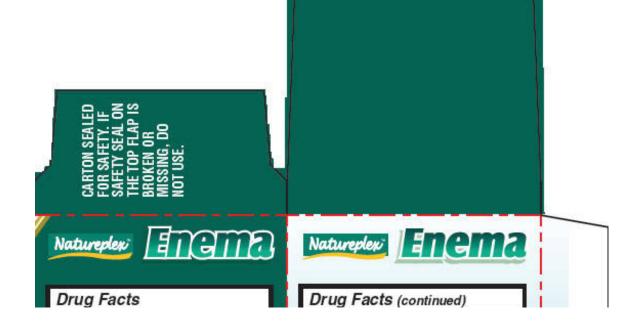


Administering enema:

- With steady pressure, gently insert enema tip into rectum with a slight sideto-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 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 you have hemorrhoids). If enema tip causes rectal bleeding or pain, get immediate medical care.
- · Squeeze bottle until nearly all liquid is







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 This product is not manufactured or distributed by C.B. Fleet Company Inc., owner of the registered trademark Fleet[®]. Directions (or as directed by a doctor)
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phosphate product.

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12 years of age and older	once daily	
Children 2 to	Use Pediatric	
under 12 years of age	Enema	
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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



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 PHO SPHATE, MO NO BASIC, UNSPECIFIED FORM (UNII: 3980 JIH2SW) (PHO SPHATE ION - UNII:NK08 V8 K8 HR, SODIUM CATION - UNII:LYR4M0 NH37)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	19 g in 133 mL		
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08 V8 K8 HR, SODIUM CATION - UNII:LYR4M0 NH37)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	7 g in 133 mL		

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			
WATER (UNII: 059QF0KO0R)			

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)	

Revised: 5/2018 Natureplex, LLC