FREDS SALINE TWIN PACK LAXATIVE- sodium phosphate, dibasic, unspecified form and sodium phosphate, monobasic, unspecified form enema FRED'S

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.

FRED'S SALINE ENEMA TWIN PACK 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 a 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.

Ask a doctor before use if you

- already used a laxative for more than 3 days
- have kidney disease, have heart problems, or are dehydrated
- are 55 years old or older
- are on a sodium-restricted diet
- have abdominal pain, nausea, or vomiting
- have a sudden change in bowel habits lasing 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 old and older	1 bottle once daily
Children 2 to under 12 years old	Use Pediatric Enema
Children under 2 years	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

DISTRIBUTED BY: fred's, Inc.

4300 NEW GETWELL RD, MEMPHIS, TN 38118

PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton

NDC 55315-301-01

fred's

Pharmacy

SALINE

enema

TWIN PACK

For Relief of

Occasional

Constipation

Ready-to-Use

Soft, Easy to use Bottle

Not Made with Natural

Rubber Latex

2

BOTTLES

4.5 FL OZ (133 mL) each

Compare To

Fleet®*

CAUTION:
REMOVE BLUE
REMOVE BLUE
PROTECTIVE
SHIELD FROM
ENEMA TIP
ENEMATION





NDC 55315-301-01



SALINE

enema

TWIN PACK

For Relief of Occasional Constipation

Ready-to-Use Soft, Easy to use Bottle Not Made with Natural Rubber Latex



SALINE

enema

TWIN PACK

For Relief of Occasional Constipation

Ready-to-Use Soft, Easy to use Bottle Not Made with Natural Rubber Latex



Compare To

CARTON SEALED FOR SAFETY. DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR

Drug Facts

Active ingredients (in each 118mL delivered dose)

Purpose

Dibasic Sodium Phosphate 7 g...... Monobasic SodiumSaline laxative Phosphate 19 g......Saline laxative

- relieves occasional constipation
 this product generally produces a 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.

Ask a doctor before use if you

- already used a laxative for more than 3 days
- have kidney disease, have heart problems, or are dehydrated
- are 55 years old or older
- are on a sodium-restricted diet
- have abdominal pain, nausea, or vomiting
 have a sudden change in bowel habits lasing 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

Drug Facts (continued)

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	1 bottle	
12 years old and older	once daily	
Children 2 to	Use Pediatric	
under 12 years old	Enema	
Children under 2 vears	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 in gredients benzalkonium chloride, disodium EDTA, purified water

Complete Enema In A

Disposable Squeeze

Bottle With Soft,

Questions or comments? 866-323-0107 or www.natureplex.com

HOW TO USE THIS ENEMA

■ REMOVE BLUE PROTECTIVE SHIELD BEFORE INSERTING. Hold bottle upright grasping bottle cap with fingers. Grasp protective shield with other hand, and pull gently to remove.



ADMINISTERING ENEMA:

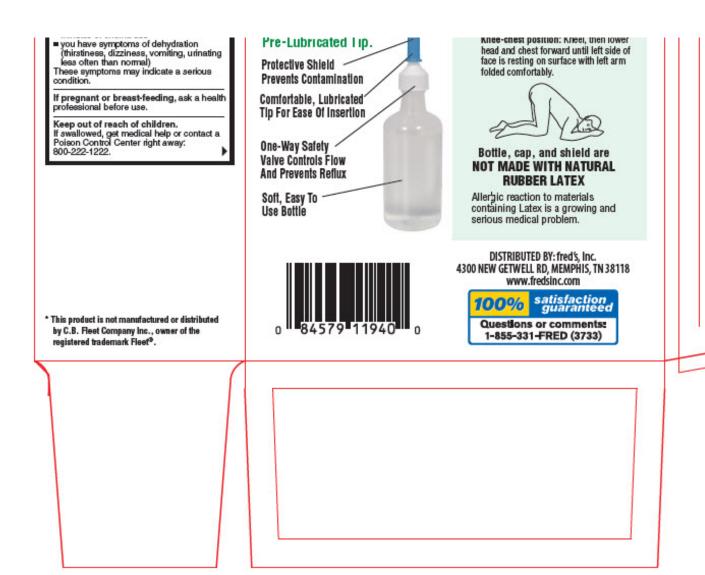
- · With steady pressure, gently insert enema tip into rectum with a slight side-to-side movement, with tip pointing toward navel. Insertion may be easier if person receiving enema. bears down, as if having a bowel movement. Doing so helps relax muscles around anus.
- · Do not force enema tip into rectum as this can cause injury.
- . 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).

POSITIONING:

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



Vana short annition. Vanal th



FREDS SALINE TWIN PACK LAXATIVE

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

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-301	
Route of Administration	RECTAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM PHO SPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR, PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHO SPHATE, DIBASIC, UNSPECIFIED FORM	7 g in 133 mL		
SO DIUM PHO SPHATE, MO NO BASIC, UNSPECIFIED FORM (UNII: 3980 JIH2SW) (PHOSPHATE ION - UNII:NK08 V8 K8 HR, SO DIUM CATION - UNII:LYR4M0 NH37)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	19 g in 133 mL		

Inactive Ingredients		
Ingredient Name Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)		

EDETATE DISODIUM	(LINII: 7EL D91C86K)

WATER (UNII: 059QF0KO0R)

ı	Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:55315-301-	2 in 1 CARTON	12/20/2019		
	1	133 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	12/20/2019	

Labeler - FRED'S (005866116)

Establishment			
Name	Address	ID/FEI	Business Operations
NATUREPLEX LLC		062808196	MANUFACTURE(55315-301)

Revised: 12/2018 FRED'S