SALINE LAXATIVE- sodium phosphate enema Walgreen Company

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.

WALGREENS READY TO USE 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
- are on a sodium-restricted diet
- 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	Use Pediatric Enema	
age		
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?

1-866-323-0107

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

PRINCIPAL DISPLAY PANEL - 133 mL Bottle Box

Walgreens Compare to Fleet[®] Enema Saline

active ingredients^{††}

NDC 0363-0005-37

READY-TO-USE Enema SALINE LAXATIVE

SALINE LAXATIVE PRE-MIXED

For relief of occasional constipation

- Lubricated tipNot made with natural rubber latex

NOT ACTUAL SIZE 4.5 FL OZ (133 mL)



SALINE LAXATIVE

sodium phosphate e							
Product Informa	tion						
Product Type					NDC:0363-00	NDC:0363-0005	
Route of Administra	ation	RECTAL					
Active Ingredien	t/Active Moi	Þtv					
		ent Name		Basis of Stre	ngth	Strengt	
SODIUM PHO SPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) SODIUM PHO SPHATE, DIB (PHO SPHATE ION - UNII:NK08V8K8HR) SODIUM PHO SPHATE, DIB					-	7 g in 118 mL	
SODIUM PHO SPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR)SODIUM PHOSPHATE, M UNSPECIFIED FORM			MONOBASIC,	19 g in 118 mL			
Inactive Ingredie	ents	. .					
Ingredient Name BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)						ength	
EDETATE DISO DIUM							
WATER (UNII: 059QF)					
Packaging							
# Item Code		Package Description		Marketing Start Date		ing End ate	
NDC:0363-0005- 37	1 in 1 BOX			0 3/11/20 16			
L	133 mL in 1 BOT	TLE; Type 0: Not a Combination F	roduct				
2 NDC:0363-0005- 38	3 in 1 BOX			0 3/11/20 16			
2	133 mL in 1 BOT Package	TLE; Type 1: Convenience Kit of C	Co-				
B NDC:0363-0005- 39	6 in 1 BOX			0 3/11/20 16			
3	133 mL in 1 BOT Package	TLE; Type 1: Convenience Kit of C	20-				

3	NDC:0363-0005- 39	6 in 1 BOX	0 3/11/20 16	
3		133 mL in 1 BOTTLE; Type 1: Convenience Kit of Co- Package		
4	NDC:0363-0005-11	1 in 1 BOX	08/31/2012	0 3/11/20 16
4		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:0363-0005- 36	3 in 1 BOX	08/31/2012	0 3/11/20 16
5		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:0363-0005- 20	6 in 1 BOX	08/31/2012	0 3/11/20 16
6		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:0363-0005- 40	24 in 1 BOX	08/31/2012	0 3/11/20 16
7		66.5 mL in 1 BOTTLE; 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 - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(0363-0005)

Revised: 1/2020

Walgreen Company