# REXALL READY TO USE 4PK LAXATIVE- sodium phosphate, dibasic, unspecified form and sodium phosphate, monobasic, unspecified form enema Dolgencorp, 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.

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## Rexall<sup>®</sup> Ready to use Enema 4pk LAXATIVE

### **Drug Facts**

Active ingredients (in each 118 mL 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 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?

Visit us at: Rexall.com or call 1-866-4-REXALL

### PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton

NDC 55910-999-06

Since 1903 Rexall®

Ready-to-Use

Enema

Saline Laxative

Sodium Phosphates

**Rectal Solution** 

### NOT MADE WITH

### NATURAL RUBBER LATEX

- For relief of occasional constipation
- Comfortable, lubricated tip
- Easy, soft squeeze bottle

4
PACK
4 Bottles
4.5 FL OZ (133 mL) Each
TOTAL 18 FL OZ (532 mL)



# Ready-to-Use **Enema**

Saline Laxative

Sodium Phosphates Rectal Solution

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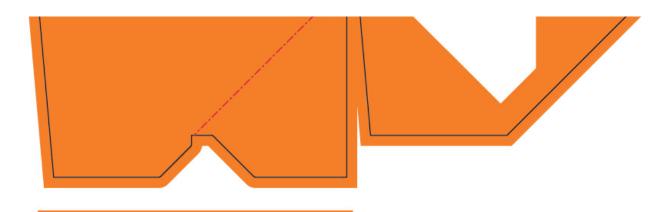
Protective shield prevents contamination

Comfortable lubricated tip for ease of insertion

One-way safety valve controls flow and prevents reflux

Soft, easy to use bottle

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Do not use more unless directed by a doctor. See Warnings.

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1 bottle once daily

# 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:

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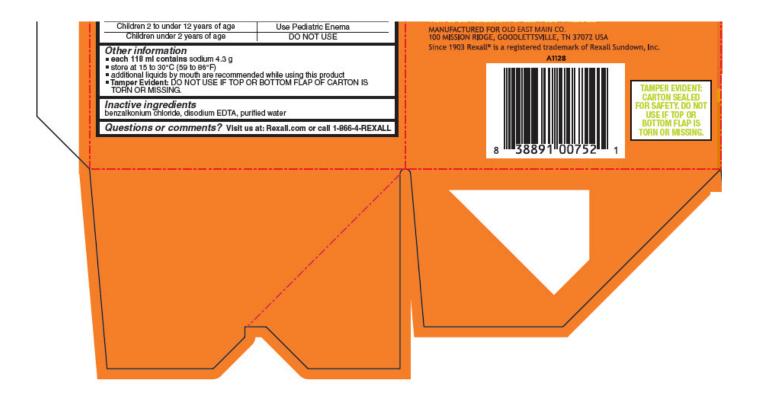
With steady pressure, gently insert enema tip into rectum with a slight side-to-side movement, with tip pointing toward navel. Insertion may be easier if person receiving enema bears down, as if having a bowel movement. Doing so helps relax muscles around anus.

Do not force enema tip into rectum. 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 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.

Bottle, cap, and shield are NOT MADE WITH NATURAL RUBBER LATEX



### REXALL READY TO USE 4PK LAXATIVE

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

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-999	
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, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	7 g in 118 mL	
SODIUM PHO SPHATE, MO NO BASIC, UNSPECIFIED FORM (UNII: 3980 JIH2S W) (PHOSPHATE ION - UNII:NK08 V8 K8 HR, SODIUM CATION - UNII:LYR4M0 NH37)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	19 g in 118 mL	

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
WATER (UNII: 059QF0KO0R)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:55910-999-	4 in 1 CARTON	06/25/2018	

1		133 mL in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package		
2	NDC:55910-999- 12	2 in 1 CARTON	06/25/2018	
2		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	06/25/2018	

## Labeler - Dolgencorp, LLC (068331990)

Establishment				
Name	Address	ID/FEI	Business Operations	
Natureplex LLC		062808196	MANUFACTURE(55910-999)	

Revised: 8/2020 Dolgencorp, LLC