LEADER READY TO USE SALINE LAXATIVE- sodium phosphate, dibasic and sodium phosphate, monobasic, unspecified form enema Cardinal Health

Leader™ Ready to Use 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

Dosage warning

Using more than one enema in 24 hours can be harmful.

For rectal use only.

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

Other information

- each 118 ml contains sodium 4.3 g
- 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

DISTRIBUTED BY CARDINAL HEALTH DUBLIN, OHIO 43017

PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton

LEADER ™

NDC 70000-0108-1

Ready-To-Use

Saline Enema Dibasic Sodium Phosphate, 7 g Monobasic Sodium Phosphate, 19 g Saline Laxative

For Relief of Occasional Constipation

Not Made with Natural Rubber Latex

COMPARE TO FLEET® SALINE ENEMA active ingredients*

1 BOTTLE

100% Money Back Guarantee

4.5 FL OZ (133 mL)

LEADER?

Ready-To-Use

Saline Enema

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TAMPER RESISTANT: DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING

PROTECTIV SHIELD FROM ENEMA TI BEFOR INSERTING

Positions for using this enema

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

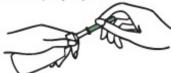


Knee-chest position: Kneel, then lower head and chest forward until left side of face is resting on surface with left arm folded comfortably.



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 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



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promptly if no liquid comes out of the rectum after 30 minutes because dehydration could COMPARE TO FLEET* SALINE **ENEMA** active ingredients" 1_{BOTTLE} 100% Money Back Guarantee Bottle, cap, and shield are **NOT MADE WITH NATURAL** 4.5 FL OZ (133 mL) **RUBBER LATEX GLUE FLAP** CARTON SEALED FOR SAFETY. IF SAFETY SEAL ON THE TOP FLAP IS BROKEN OR MISSING, DO NOT USE. NO COLOR / TEXT **NO COATING Drug Facts** Drug Facts (continued)

Directions (or as directed by a doctor)
Single daily dosage (per 24 hours)
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phosphate product.
Do not use more unless directed by a

Active ingredients P. (in each 118mL delivered dose)

Phosphate 7 gSaline laxative

Dibasic Sodium

Purpose

Phosphate 19 gSaline laxative

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CardinalHealth™

Essential to Care™ since 1979



All LEADER™ Brand Products Have A 100% Money Back Guarantee

Return to place of purchase if not satisfied.

doctor, See Warnings,

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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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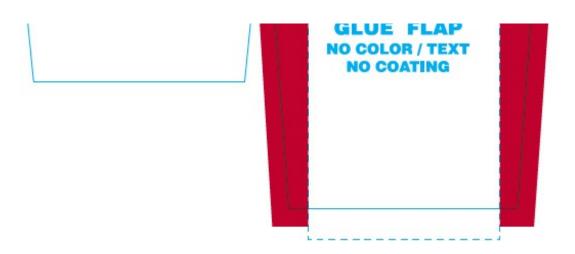
Questions or comments? 866-323-0107

Protective shield prevents contamination Comfortable, ubricated tip for ease of insertion One-way safety valve controls flow and prevents reflux Easy, soft squeeze bottle

CIN 5205489

REV. 7/20





LEADER READY TO USE SALINE LAXATIVE

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

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0108
Route of Administration	RECTAL		

Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	sphate, Dibasic, Unspecified Form (UNII: GR686LBA74) ION - UNII:LYR4M0NH37, PHOSPHATE ION - UNII:NK08V8K8HR)	Sodium Phosphate, Dibasic, Unspecified Form	7 g in 118 mL	
	sphate, Monobasic, Unspecified Form (UNII: 3980JIH2SW) ION - UNII:LYR4M0NH37, PHOSPHATE ION - UNII:NK08V8K8HR)	Sodium Phosphate, Monobasic, Unspecified Form	19 g in 118 mL	

Inactive Ingredients			
Ingredient Name Streng			
Benzalkonium Chloride (UNII: F5UM2KM3W7)			
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)			
Water (UNII: 059QF0KO0R)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:70000- 0108-1	1 in 1 CARTON	02/19/2013		
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:70000- 0108-2	2 in 1 CARTON	02/19/2013		
2		133 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 drug	M007	02/19/2013	

Labeler - Cardinal Health (063997360)

Establishment				
Name	Address	ID/FEI	Business Operations	
Natureplex LLC		062808196	MANUFACTURE(70000-0108)	

Revised: 12/2024 Cardinal Health