

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

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.

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 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** 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 TM

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)

CAUTION:
REMOVE GREEN
PROTECTIVE
SHIELD FROM
ENEMA TIP
BEFORE
INSERTING.
PL31300B
V03

Positions for using this enema

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

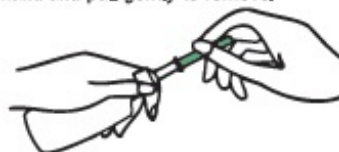


Knee-chest position: Kneel, then lower head and chest forward until left side of face is resting on surface with left arm folded comfortably.



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

LEADER²

Ready-To-Use

Saline Enema

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

TAMPER RESISTANT: DO NOT USE IF TOP OR
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LEADER²

NDC 70000-0100-1

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



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**

**COMPARE TO
FLEET® SALINE
ENEMA**
active ingredients*

**100% Money
Back Guarantee**

1 BOTTLE

4.5 FL OZ (133 mL)

**CARTON SEALED
FOR SAFETY. IF
SAFETY SEAL ON
THE TOP FLAP IS
BROKEN OR
MISSING, DO
NOT USE.**

**GLUE FLAP
NO COLOR / TEXT
NO COATING**

Drug Facts

Active ingredients Purpose
(in each 118mL delivered dose)

Dibasic Sodium
Phosphate 7 gSaline laxative
Monobasic Sodium

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

Phosphate 19 gSaline laxative

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Warnings

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Inactive ingredients

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Questions or comments?

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Protective shield
prevents
contamination

Comfortable,
lubricated tip for
ease of insertion

One-way safety valve
controls flow and
prevents reflux

Easy, soft squeeze
bottle



GLUE FLAP: NO COLOR / TEXT / NO COATING

*This product is not manufactured or distributed by C.B. Reet Company Inc., owner of the registered trademark Reet®.

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DUBLIN, OHIO 43017
www.myleader.com
1-800-200-6313

Essential to Care™ since 1979



CardinalHealth™

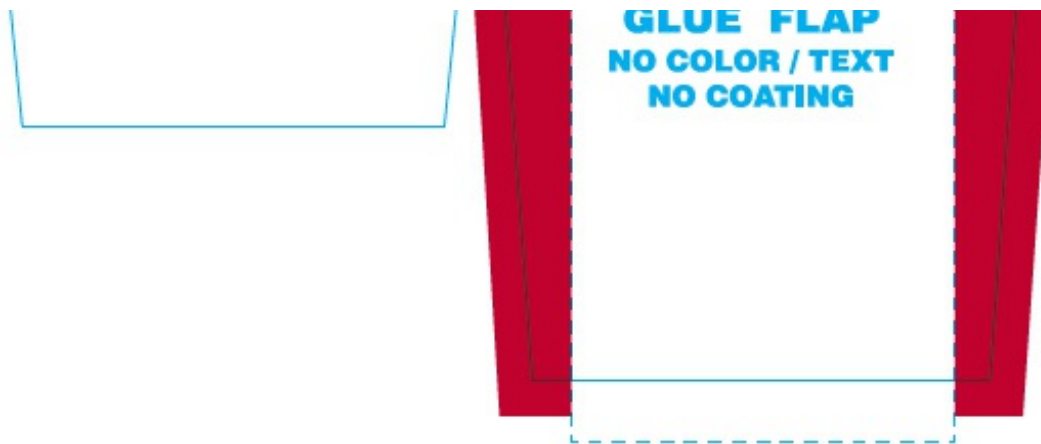
CIN 5205489

REV. 7/20



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

Return to place of purchase if not satisfied.



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
Sodium Phosphate, Dibasic, Unspecified Form (UNII: GR686LBA74) (SODIUM CATION - UNII:LYR4M0NH37, PHOSPHATE ION - UNII:NK08V8K8HR)	Sodium Phosphate, Dibasic, Unspecified Form	7 g in 118 mL
Sodium Phosphate, Monobasic, Unspecified Form (UNII: 3980JIH2SW) (SODIUM CATION - UNII:LYR4M0NH37, PHOSPHATE ION - UNII:NK08V8K8HR)	Sodium Phosphate, Monobasic, Unspecified Form	19 g in 118 mL

Inactive Ingredients

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

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 NOT FINAL	part334	02/19/2013	

Labeler - Cardinal Health (063997360)

Establishment

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

Revised: 6/2021

Cardinal Health