

LEADER ENEMA- saline enema
CARDINAL HEALTH, INC.

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.

Active ingredients (in each 118 mL delivered dose)

Dibasic sodium phosphate 7 g

Monobasic sodium phosphate 19 g

Purpose

Saline laxative

Uses

- relieves occasional constipation

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 have

- a sodium-restricted diet
- abdominal pain, nausea or vomiting
- kidney disease, heart problems, or are dehydrated
- noticed a sudden change in bowel habits that lasts over 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

Stop use and ask a doctor if

- you have rectal bleeding
- you have no bowel movement after use of a laxative

These could be signs of 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. (1-800-222-1222)

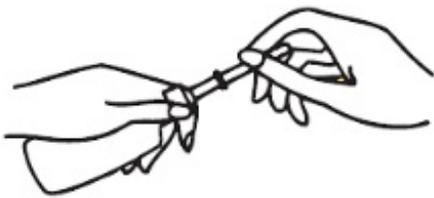
Directions

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

adults & children 12 years and over	one bottle once daily
children 2 to under 12 years	½ bottle once daily
children under 2 years	do not use

Caution:

REMOVE GREEN PROTECTIVE SHIELD BEFORE INSERTING; HOLD BOTTLE UPRIGHT, GRASPING BOTTLE CAP WITH FINGERS. GRASP PROTECTIVE SHIELD WITH OTHER HAND AND PULL GENTLY TO REMOVE.



Positioning:

Left-side position: Lie on left side with knee bent and arms at rest.



Knee-chest position:

Kneel, then lower head and chest forward until left side of face is resting on surface. Position arms comfortably.



Administering enema:

- With steady pressure, gently insert enema with tip pointing toward navel

- squeeze bottle until recommended dose is expelled (it is not necessary to empty until completely. Bottle contains more liquid than needed for effective use. A small amount of liquid will remain in bottle after squeezing).
- Remove tip from rectum.
- stop using if tip is hard to insert. Forcing the tip into rectum can cause injury (especially if you have hemorrhoids). If enema tip causes rectal bleeding or pain, get immediate medical care.
- maintain 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.

Other information

- each 118 mL contains: sodium 4.3 g
- store at room temperature 20°-25°C (68°-77°F)
- this product generally produces bowel movement in 1 to 5 minutes

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

1-800-367-4477

Principal Display Panel

Leader

Compare to Fleet® Enema Saline active ingredients

READY-TO-USE

Enema

Saline Laxative

For Relief Of Occasional Constipation

Soft, Flexible Comfort Tip

Latex Free

4.5 FL OZ (133ml)

Drug Facts (continued)

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

1-800-633-5463

CAUTION: Remove green protective shield before inserting; hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with other hand and pull gently to remove.



Positioning:

Left-side position: lie on left side with knee bent and arms at rest.



Knee-chest position: kneel, then lower head and chest forward until left side of face is resting on surface. Position arms comfortably.



Administering enema:

- with steady pressure, gently insert enema with tip pointing toward navel
- squeeze bottle until recommended dose is expelled (it is not necessary to empty unit completely. Bottle contains more liquid than needed for effective use. A small amount of liquid will remain in bottle after squeezing).
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All Leader® Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
CIN 4725495
www.myleader.com
1-800-200-6313

Made in USA RJ12MLW [REF] CRD-PH-1-24N



*This product is not manufactured or distributed by C.B. Fleet Co., Inc., the distributor of Fleet® Enema Saline.

NDC 37205-754-11



Compare to Fleet®
Enema Saline
active ingredients*

READY-TO-USE

Enema

Saline Laxative

For Relief Of
Occasional
Constipation

Soft, Flexible
Comfort Tip

Latex Free



4.5 FL OZ (133 ml)

Package Label - Back and Side Label with Drug Facts

LEADER®

Compare to Fleet®
Enema Saline
active ingredients*

READY-TO-USE

Enema

Saline Laxative

For Relief Of
Occasional
Constipation

Soft, Flexible
Comfort Tip

Latex Free

Protective shield
prevents
contamination

Comfortable,
lubricated tip for
ease of insertion

One-way safety valve
controls flow and
prevents reflux

Easy, soft squeeze
bottle



4.5 FL OZ (133 ml)

TEP

TAMPER EVIDENT: CARTON SEALED FOR SAFETY.
IF PRINTED SEAL ON BOTTOM OR TOP FLAP IS
BROKEN OR MISSING, DO NOT USE.

Drug Facts

Active ingredients

(in each 118 mL
delivered dose)

Purpose

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These could be signs of 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. (1-800-222-1222)

Directions

Do not use more unless directed by a doctor.

See Warnings.

adults & children 12 years and over	one bottle once daily
children 2 to under 12 years	1/2 bottle once daily discard unused portion
children under 2 years	do not use

Other information

- each 118 mL contains: sodium 4.3 g
- store at room temperature 20°-25°C (68°-77°F)
- this product generally produces bowel movement in 1 to 5 minutes

TEP

LEADER ENEMA

saline enema

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:37205-754

Route of Administration

RECTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC	7 g in 118 mL
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC	19 g in 118 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-754-11	1 in 1 CARTON		
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:37205-754-36	2 in 1 CARTON		
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, INC. (097537435)

Revised: 6/2015

CARDINAL HEALTH, INC.