SALINE ENEMA- sodium phosphate monobasic, sodium phosphate dibasic enema
Dynarex Corporation

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.

4719 Enema, Saline NDC 67777-402-01

Active Ingredients

(in each 118 mL delivered dose)

Dibasic Sodium Phosphate 7g

Monobasic Sodium Phosphate 19g

Purpose

Saline Laxative

Uses

• For relief of occasional constipation

• This product generally produces bowel movement in 2 to 15 minutes

Warnings:

For rectal use only

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

Do not use

• Laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor

• Longer than 1 week unless directed by a doctor

• This product if you are on a low salt diet unless directed by a doctor

• This product if you have kidney disease unless directed by a doctor

Ask a doctor before use if you have:

Noticed a sudden change in bowel habits that persists over a period of 2 weeks

Stop use and ask a doctor if:

- If you have rectal bleeding or fail to have a bowel movement after use

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Adults and children 12 years old and over - 1 bottle once daily

Children 2 to under 12 years of age - 1/2 bottle once daily, discard unused portion

Children under 2 years - Consult a physician.

Other information:

- Sodium content in each dose (1 bottle): 4.4 g
- Store at room temperature 15º-30ºC (59º- 8ºF)

Inactive ingredients

Benzalkonium Chloride, Disodium EDTA, Purified Water

Questions?

1-888-DYNAREX Monday - Friday 9AM - 5PM EST

Label

ENEMA
SALINE LAXATIVE
Ready-To-Use

TAMPER EVIDENT:
IF THE TOP OR BOTTOM FLAP IS TORN OR DAMAGED IN ANY WAY, 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 unit 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 the 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.

7.3 in.

We Care™ from dynarex

ENEMA
SALINE LAXATIVE
Ready-To-Use

Soft, Flexible, Comfortable, Lubricated Tip

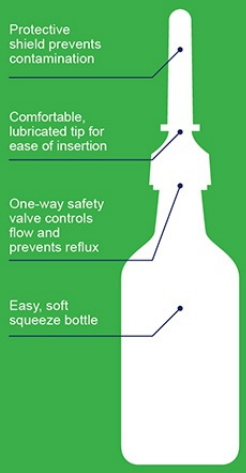
- For Relief of Occasional Constipation
- Pre-mixed

1 4.5 fl. oz. (133 mL)

We Care™ from dynarex

ENEMA
SALINE LAXATIVE
Ready-To-Use

Soft, Flexible, Comfortable, Lubricated Tip



1 4.5 fl. oz. (133 mL)

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

Uses
- For relief of occasional constipation
- This product generally produces bowel movement in 2 to 15 minutes

Warnings

For rectal use only

Do not use
- Laxative products when abdominal pain, nausea, or vomiting are present unless directed by a doctor
- Longer than 1 week unless directed by a doctor
- This product if you are on a low salt diet unless directed by a doctor
- This product if you have kidney disease unless directed by a doctor

Ask a doctor before use if you have noticed a sudden change in bowel habits that persists over a period of 2 weeks

Stop use and ask a doctor if you have rectal bleeding or fail to have a bowel movement after use

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Adults and children 12 years old and over	1 bottle once daily
Children from 2 to under 12 years of age	½ bottle once daily, discard unused portion
Children under 2 years old	Consult a doctor

Other Information
- Store at room temperature 15°-30°C (59°-86°F)
- Sodium content in each dose (1 bottle): 4.4 g

Inactive Ingredients
Benzalkonium Chloride, Disodium EDTA, Purified Water

Questions? 1-888-DYNAREX Monday - Friday 9AM – 5PM EST

Reorder No. 4719

Manufactured for: Dynarex Corporation
10 Glenshaw Street • Orangeburg, NY 10962
USA • www.dynarex.com

Made in India

LOT LLLLL

YYYY-MM-DD

YYYY-MM-DD

SYMBOL GLOSSARY
For an explanation of symbols used in Dynarex packaging, visit dynarex.com/symbols.php

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TAMPER EVIDENT:
IF THE TOP OR BOTTOM FLAP IS TORN OR DAMAGED IN ANY WAY, DO NOT USE

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4719 Enema Saline Laxative

SALINE ENEMA

sodium phosphate monobasic, sodium phosphate dibasic enema

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-402
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-402-02	48 in 1 CASE	08/29/2012	
1	NDC:67777-402-01	1 in 1 BOX		
1		118 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	08/29/2012	

Labeler - Dynarex Corporation (008124539)

Registrant - Dynarex Corporation (008124539)

Revised: 11/2022 Dynarex Corporation