

QUALITY CHOICE SINGLE SALINE LAXATIVE- sodium phosphate, dibasic, unspecified form and sodium phosphate, monobasic, unspecified form enema
Alcyon Health, 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.

**QUALITY CHOICE SINGLE SALINE ENEMA
LAXATIVE**

Drug Facts

Active ingredients (in each 118 mL delivered dose)	<i>Purpose</i>
Dibasic Sodium Phosphate 7 g	Saline laxative
Monobasic Sodium Phosphate 19 g	Saline laxative

Use

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

- already used a laxative for more than 1 week
- are dehydrated
- have kidney disease
- are 55 years old or older
- have heart problems
- are on a sodium-restricted diet

Ask a doctor before using any laxative if you have

- abdominal pain, nausea, or vomiting
- a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more than 1 week

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 bleeding
- the condition worsens or does not improve within 7 days
- 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.

Directions

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 old and older	1 bottle once daily
Children 2 to under 12 years old	1/2 bottle once daily
Children under 2 years	DO NOT USE

Other information

- **each 118 ml contains** 4.4 g sodium
 - store at 15 to 30°C (59 to 86°F)
 - additional liquids by mouth are recommended while using this product
 - this product generally produces a bowel movement in 1 to 5 minutes
- carton sealed for safety. Do not use if the top or bottom flap of the carton is torn or missing**

Inactive ingredients

Benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

1-844-624-2633 or www.maiaimed.com

Distributed By:

Maia Medical

655 Metro Place South, Suite 600-050

Dublin, OH 43017 USA

PRINCIPAL DISPLAY PANEL - 133 ml Bottle Carton

maia
medical™

SALINE
enema

6 Bottles
4.5 Fl Oz (133 ml) each

Latex Free

Tamper Resistant
Do not use if top or bottom flap
of carton is torn or missing.

SALINE enema

Latex Free

CAUTION:
REMOVE BLUE
PROTECTIVE
SHIELD FROM
ENEMA TIP
BEFORE
INSERTING.
PL32651B
V01



How To Use This Enema

REMOVE BLUE PROTECTIVE SHIELD 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. This helps relax the muscles around the anus.
- Do not force the enema tip into rectum as this may cause injury.
- Squeeze bottle until nearly all liquid is gone. It is not necessary to empty the bottle completely, as it contains more liquid than needed.
- Remove tip from rectum and maintain position until urge to evacuate is strong (usually 1 to 15 minutes).
- Discontinue use if resistance is encountered; forcing the enema can result in injury.

POSITIONING:

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

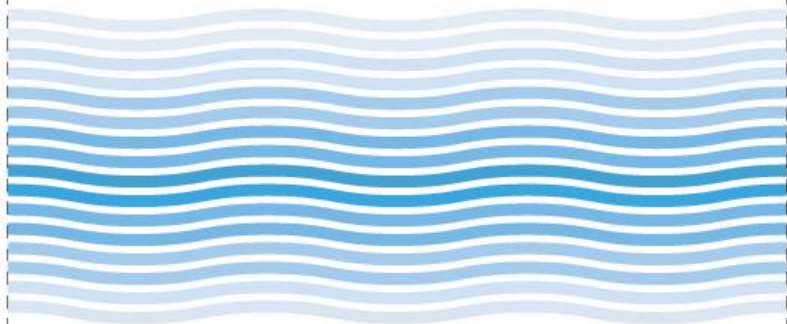
Knee-chest position: Kneel, then lower head and chest forward until left side of face is resting on surface. Position arms comfortably.



Distributed By:
Mata Medical
655 Metro Place South, Suite 600-050
Dublin, OH 43017 USA
maimed.com • 1-844-624-2633



SALINE enema



6 Bottles
4.5 Fl Oz (133 ml) each

Latex Free

lot encoding zone
no ink, no coating

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

fulfillment glue zone
no ink, no coating

SALINE enema

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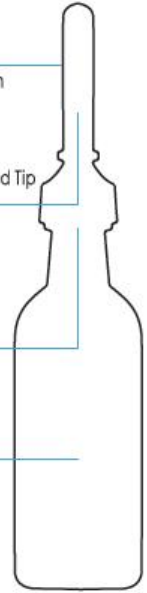
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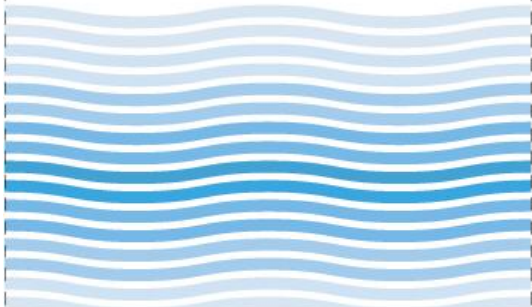
Questions or comments? 1-844-624-2693 or www.mallmed.com

Complete Enema In A Disposable Squeeze Bottle With Soft, Pre-Lubricated Tip.



neff glue zone
no ink, no coating

SALINE enema



Bottles
4.5 FL Oz (133 mL) each

Latex Free



fulfillment glue zone
no ink, no coating

QUALITY CHOICE SINGLE SALINE LAXATIVE
 sodium phosphate, dibasic, unspecified form and sodium phosphate, monobasic, unspecified form enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71443-001
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 (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71443-001-06	6 in 1 CARTON	07/05/2017	
1		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	07/05/2017	

Labeler - Alcyon Health, LLC. (080040408)**Establishment**

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(71443-001)

Revised: 7/2017

Alcyon Health, LLC.