

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

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

<i>Active ingredients (in each 118mL delivered dose)</i>	<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
- have kidney disease
- have heart problems
- are dehydrated
- are 55 years old or older
- 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: 800-222-1222.

Directions

Single daily dosage (per 24 hours)

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

Do not use if taking another sodium phosphate product.

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 top or bottom flap of the carton is torn or missing**

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

866-323-0107 or www.natureplex.com

Distributed by C.D.M.A., Inc.©
43157 W. Nine Mile
Novi, MI 48376-0995

PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton

NDC# 63868-380-45

QC[®]
QUALITY
CHOICE

* Compare to the
active ingredients
in FLEET[®] Enema

Enema

**Relieves Occasional
Constipation**

Complete, Ready-to-Use

SODIUM PHOSPHATES

RECTAL SOLUTION

Latex Free

Comfortable,
Lubricated Tip

Works In
Minutes

1
Bottle
4.5 Fl Oz (133 mL)

CAUTION:
REMOVE BLUE
PROTECTIVE
SHIELD FROM
ENEMA TIP
BEFORE
INSERTING

Enema
QUALITY CHOICE
For Relief Of Occasional Constipation
Tamper Resistant
Do not use if safety seal on the top flap is broken or missing.

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

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.



■ **POSITIONING:**
Left-side position: Lie on left side with knee 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.



■ **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 the muscles around anus.
- **Do not force enema tip into rectum as this can cause injury.**
- 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).

Bottle, cap and shield are Latex Free

Allergic reaction to materials containing Latex is a growing and serious medical problem.



QC QUALITY CHOICE
NDC# 39868-390-45
* Compare to the active ingredients in FLEET® Enema

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RECTAL SOLUTION

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

QC QUALITY CHOICE

Enema

Relieves Occasional Constipation

Complete, Ready-to-Use

SODIUM PHOSPHATES
RECTAL SOLUTION

Drug Facts (continued)

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100% SATISFACTION GUARANTEED
QC QUALITY CHOICE
Distributed by C.D.M.A., Inc.®
43157 W. Nine Mile
Novi, MI 48376-0995
www.qualitychoice.com
Questions: 248-449-9300

QUALITY CHOICE SINGLE SALINE LAXATIVE

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-380
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, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII: NK08V8K8HR, SODIUM CATION - UNII: LYR4M0NH37)	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: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-380-45	1 in 1 CARTON	06/01/2010	
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:63868-380-90	2 in 1 CARTON	06/01/2010	
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	06/01/2010	

Labeler - CDMA (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(63868-380)