

SUNMARK SALINE SINGLE LAXATIVE- sodium phosphate, dibasic and sodium phosphate, monobasic, unspecified form enema

Strategic Sourcing Services 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.

Sunmark® Saline Enema Single 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
- 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?

1-800-633-5463

**Distributed By Strategic Sourcing Services LLC
6555 State Highway 161, Irving, TX 75039**

PRINCIPAL DISPLAY PANEL - 133 ml Bottle Carton

sunmark®

COMPARE TO
FLEET® ENEMA SALINE
ACTIVE INGREDIENTS*

NDC 49348-186-20

complete &
ready-to-use
enema
Saline Laxative

For relief of
occasional constipation

Soft, flexible
Comfort tip

Pre-mixed

LATEX FREE

4.5 FL OZ
(133 ml)

PL31353B
V02

complete & ready-to-use
enema
Saline Laxative
sunmark®

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ACTIVE INGREDIENTS*

NDC 49348-186-20

complete & ready-to-use
enema
Saline Laxative

For relief of occasional constipation
Soft, flexible Comfort tip
Pre-mixed

Protective shield prevents contamination

Comfortable, lubricated tip for ease of insertion

One-way safety valve controls flow and prevents reflux

Easy, soft squeeze bottle



LATEX FREE

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 Purpose
(in each 118mL delivered dose)
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, or 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.

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Other information
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store at 15 to 30°C (59 to 86°F)
additional liquids by mouth are recommended while using this product

Drug Facts (continued)

■ 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?
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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 promptly if no liquid comes out of the rectum after 30 minutes because dehydration could occur.

MCKESSON

Another Quality Product
Distributed by Strategic Sourcing Services LLC
6066 State Highway 161, Irving, TX 75039
Money Back Guarantee
Please visit us at www.sunmarkbrand.com
NDC15CTR

REF MCK-PH-1-24N



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

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SUNMARK SALINE SINGLE LAXATIVE

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-186
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) (Phosphate Ion - UNII:NK08V8K8HR, Sodium Cation - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	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: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-186-20	1 in 1 CARTON	03/06/2013	
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49348-186-14	2 in 1 CARTON	03/06/2013	
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	03/06/2013	

Labeler - Strategic Sourcing Services LLC (116956644)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(49348-186)

Revised: 7/2020

Strategic Sourcing Services LLC