SUNMARK SALINE SINGLE LAXATIVE- sodium phosphate, dibasic and sodium phosphate, monobasic, unspecified form enema Strategic Sourcing Services LLC

Sunmark[®] Saline Enema Single Laxative

Drug Facts

Active ingredients (in each 118mL delivered dose)	Purpose	
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	1 bottle
of age and older	once daily
Children 2 to under 12 years	Use Pediatric
of age	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)

닯 1353B V02

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?

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.



dministering enema:

- Admitisation general. With stady pressure gently insert enema by into rectum with a slight side-to-side movement, with tip polithing toward rate. Insertion may be easier if person receiving end may be as the wind a bowel movement. Doing so helps relax muscles around arus.
- 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 enematical pusses rectal bleeding or pain, get immediate medical
- Squeeze bottle until nearly all liquid is gone. It is not necessary to empty bottle completely, as it conta more liquid than needed.
- Acronev fight of security and stay in position until urge to execute its strong usually 1 to 5 minutes). If no urge is left affer 5 minutes of using, try to empty bowel. Call a doctor promptly fin oil iguid comes cut of the necturn after 30 minutes because dehydration could occur.

MSKESSON

REF MCK-PH-1-24N



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

Saline Laxafive

euewa

ready-to-use complete &

sunmark



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NDC 49348-186-20

complete & ready-to-use

enema

Saline Laxative

For relief of occasional constipation

> Soft, flexible Comfort tip

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4.5 FL OZ (133 ml) sun mark*

COMPARE TO FLEET® ENEMA SALINE ACTIVE INGREDIENTS*

NDC 49348-186-20

complete & ready-to-use

enema

Saline Laxative

For relief of constipution

> Soft, flexible Comfort tip

> > Pre-mixed

lubricated tip for

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

Purpose

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Warnings

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

For rectal use only.

Do not use son 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
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 lasting more than 2 weeks

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. Ask a doctor or pharmacist before use

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 enems 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

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.

12 years of age and older	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

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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)			

P	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 drug	M007	03/06/2013	

Labeler - Strategic Sourcing Services LLC (116956644)

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