

SUNMARK- saline laxative enema
Mckesson 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.

Active ingredients (in each 118 mL delivered dose)

Dibasic sodium phosphate 7 g

Monobasic sodium phosphate 19 g

Purpose

Saline laxative

Uses

- 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 have

- a sodium-restricted diet
- abdominal pain, nausea or vomiting
- kidney disease, heart problems, or are dehydrated
- noticed a sudden change in bowel habits that lasts over 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

Stop use and ask a doctor if

- you have rectal bleeding
- you have no bowel movement after use of a laxative

These could be signs of 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. (1-800-222-1222)

Directions

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

| | |
|-------------------------------------|-----------------------------------------------|
| adults & children 12 years and over | one bottle once daily |
| children 2 to under 12 years | ½ bottle once daily Discard unused portion |
| children under 2 years | 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 until 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 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.

Other information

- each 118 mL contains: sodium 4.3 g
- store at room temperature 20°-25°C (68°-77°F)
- this product generally produces bowel movement in 1 to 5 minutes

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

1-800-633-5463

Principal Display Panel

Sunmark

Compare to Fleet® Enema Saline active ingredients*

NDC 49348-864-20

Complete and ready-to-use

Enema

Saline Laxative

For Relief Of Occasional Constipation

Soft, Flexible Comfort Tip

Pre-mixed

LATEX FREE

4.5 FL OZ (133ml)

TEP

Saline Laxative

enema
ready-to-use
& complete

sunmark

sunmark®

COMPARE TO
FLEET® ENEMA SALINE
ACTIVE INGREDIENTS*

NDC 49348-864-20

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)

Drug Facts (continued)

Inactive ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions or comments?

1-800-633-6463

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.

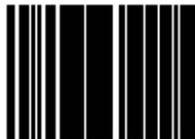


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McKesson

Active Quality Product
Distributed by McKesson
One First Street, San Francisco, CA 94104
Neosoy Back Guarantee
Please visit us at www.sunmarkread.com
Made in USA FR13CTR
[REF] MCK-PH-1-24N



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

Package Label - Back and Side Label with Drug Facts

sunmark®

COMPARE TO
FLEET® ENEMA SALINE
ACTIVE INGREDIENTS*
NDC 49348-864-20

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)

TEP

**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 |

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TEP

SUNMARK

saline laxative enema

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49348-864

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 (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37) | SODIUM PHOSPHATE, MONOBASIC | 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:49348-864-20 | 1 in 1 CARTON | | |
| 1 | | 133 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:49348-864-14 | 2 in 1 CARTON | | |
| 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 - Mckesson Corporation (177667227)

Revised: 6/2015

Mckesson Corporation