**SALINE LAXATIVE- sodium phosphate enema**
**Supervalu Inc**

*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.*

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## Drug Facts

### Active ingredient

(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 may be signs of a serious condition.

**If pregnant or breastfeeding, 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<br>12 years and over | one bottle once daily |
| children 2 to under<br>12 years | 1/2 bottle once daily<br>Discard unused portion |
| children under<br>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 unit 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 the 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 deg C (68-77 deg 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

**Side and Principal Display Panel - box**

**Drug Facts** (continued)

***Inactive ingredients***
benzalkonium chloride, disodium EDTA, purified water

***Questions or comments?***
**1-877-932-7948**

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.

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

NDC 41163-005-11

compare to Fleet® Enema Saline active ingredients*

EQUALINE®

complete and ready-to-use

# enema

saline laxative

for relief of occasional constipation

- *pre-mixed*
- *soft, flexible comfort tip*

1 BOTTLE
4.5 FL OZ
(133mL)

NDC 41163-005-11

Compare to Fleet Enema Saline active ingredients

Equaline

Complete and Ready-to-Use

**ENEMA**

Saline Laxative

For relief of occasional constipation

Pre-mixed

Soft, flexible comfort tip

1 Bottle

4.5 FL OZ (133 ml)

**Side and Back - box**

EQUALINE®

complete and ready-to-use

# enema

saline laxative

for relief of occasional constipation

• *this item is not made with natural rubber latex*

**DISTRIBUTED BY SUPERVALU INC.**
**EDEN PRAIRIE, MN 55344**
**MADE IN USA RD14CTR**
**REF EQU-PH-1-24N**

SUPERVALU QUALITY Guaranteed

**Contact us at 1-877-932-7948, or www.supervalu-ourownbrands.com**

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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**If pregnant or breast-feeding,** ask a health professional before use.

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### *Directions*

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***Questions or comments?***
**1-877-932-7948**

TEP

# SALINE LAXATIVE

sodium phosphate enema

| **Product Information** | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:41163-005 |

| Route of Administration | RECTAL |
|---|---|

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **SODIUM PHOSPHATE, DIBASIC** (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR) | SODIUM PHOSPHATE, DIBASIC | 7 g in 118 mL |
| **SODIUM PHOSPHATE, MONOBASIC** (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR) | 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:41163-005-11 | 1 in 1 BOX | | |
| **1** | | 133 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| **2** | NDC:41163-005-35 | 2 in 1 BOX | | |
| **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 | 08/31/2012 | |

## Labeler - Supervalu Inc (006961411)

Revised: 6/2015 Supervalu Inc