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.

Saline 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

For rectal use only.

Dosage warning

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

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

- vou 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 4.3 g sodium
- 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?

1-877-932-7948

DISTRIBUTED BY SUPERVALU INC. EDEN PRAIRIE, MN 55344

PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton

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

- premixed
- soft, flexible

comfort tip

1 BOTTLE 4.5 FL OZ (133mL) saline laxative

ewews

complete and ready-to-use

ESONTINE.

PL31151B V03

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

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

- 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.



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

- premixed
- soft, flexible comfort tip

1BOTTLE 4.5 FL OZ (133mL)



complete and

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 118mL delivered dose) Dibasic Sodium

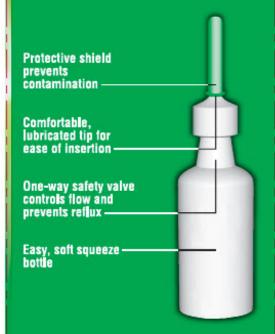
Purpose

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



Like it or let us make it right. That's our quality promise. 877-932-7948 supervaluprivatebrands.com Phosphate 7 gSaline laxative
Monobasic Sodium
Phosphate 19 gSaline laxative

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Warnings

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

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

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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.

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Inactive ingredients
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purified water

Questions or comments? 1-877-932-7948

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 PHO SPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM	7 g in 118 mL		
SODIUM PHO SPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM	19 g in 118 mL		

Inactive Ingredients			
Ingredient Name	Strength		
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			
WATER (UNII: 059QF0KO0R)			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41163-005-11	1 in 1 BOX	08/31/2012		
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:41163-005-35	2 in 1 BOX	08/31/2012		
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)

Establishment			
Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(41163-005)

Revised: 1/2019 Supervalu Inc