ORAL SALINE LAXATIVE- dibasic sodium phosphate, monobasic sodium phosphate liquid 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.

Drug Facts

Active ingredient (in each tablespoon)

Dibasic sodium phosphate 2.7 g

Monobasic sodium phosphate 7.2 g

Purpose

Saline laxative

Use

• for relief of occasional constipation

Warnings

Dosage warning

Taking more than the recommended dose in 24 hours can be harmful.

Do not use

- if you have a previous kidney problem, congestive heart failure, impaired renal functions, decreased intervascular volume, dehydration, uncorrected electrolyte abnormalities
- in children under 5 years of age
- for bowel cleansing

Ask a doctor before use if you have

- abdominal pain, nausea, or vomiting
- kidney disease
- heart problems
- a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more than a week
- a dehydration condition

Ask a doctor or pharmacist before use if you are

- on a sodium restricted diet
- under a doctor's care for any medical condition
- taking any other prescription or non-prescription medications. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if you

- have any rectal bleeding
- do not have a bowel movement within 6 hours
- have any symptoms that your body is losing more fluid than you are drinking
- have early symptoms of dehydration including feeling thirsty, dizziness, urinating less often than

normal, vomiting. These symptoms may indicate a serious condition.

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

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- use as a laxative for relief of occasional constipation
- **dilute dose in the table below** with one glass (8 fl. oz.) cool water. Drink, then follow with at least one additional glass (8 fl. oz.) cool water. **There is significant loss of liquid when using this product.** To prevent dehydration drink plenty of clear liquid after use.
- Do not use for bowel cleansing.
- Do not take more unless directed by a doctor. See Warning. There are three Teaspoons in one Tablespoon.
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Ages (Years)	Dosage	Maximum Dose
12 & Older	3 Teaspoons	6 or 9 Teaspoons*
10 & 11	3 Teaspoons*	3 Teaspoons*
5 to 9	1 1/2 Teaspoons*	1 1/2 Teaspoons*
under 5	Do Not Use	Do Not Use

***SINGLE DAILY DOSAGE. DO NOT TAKE MORE OF THIS PRODUCT IN A 24-HOUR PERIOD**

Other information

- Each Teaspoon contains: sodium 556 mg
- Saline laxatives increase retention of water in the intestine, promoting bowel movements.
- this product generally produces a bowel movement in 30 minutes to 6 hours
- this product is sugar free
- do not freeze
- store at room temperature

TAMPER EVIDENT: Mouth of bottle sealed for your safety. If foil seal is missing or broken, do not use.

Inactive ingredients

Ginger lemon flavor, glycerin, purified water, saccharin sodium, sodium benzoate

Questions

1-800-633-5463

Package/Label Principal Display Panel



equaline NDC 41163-111-12 **oral saline laxative** fFor relief of occasional constipation

single dose container

ginger lemon flavor

1.5 FL OZ (45 mL)

Package Drug Facts 1

Drug Facts

Active ingredients (in each Tablespoon)

Purpose

Drug Facts (continued)

Use for relief of occasional constipation

Warnings

Dosage warning

Taking more than the recommended dose in 24 hours can be harmful. Do not use if you have a previous kidney problem, congestive heart failure,

impaired renal functions, decreased intervascular volume, dehvdration, uncorrected electrolyte abnormalities in children under 5 years of age for bowel cleansing

Ask a doctor before use if you have abdominal pain, nausea, or vomiting kidney disease a heart problems a sudden change in bowel habits lasting more than 2 weeks already used a laxative for more than a week a dehydration condition

Ask a doctor or pharmacist before use if you are on a sodium restricted diet under a doctor's care for any medical condition a taking any other prescription or non-prescription medications. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

Drug Facts (continued)

Stop use and ask a doctor if you a have any rectal bleeding do not have a bowel movement within 6 hours a have any symptoms that your body is losing more fluid than you are drinking have early symptoms of dehydration including • feeling thirsty • dizziness • urinating less often than normal . vomiting. These symptoms may indicate a serious condition.

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately.

Drug Facts (continued)

Directions

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Package Drug Facts 2

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ORAL SALINE L								
libasic sodium phospha	te, monobasic sodium phosphat	te liquid						
Product Information	1							
Product Type	HUMAN OTC DRUG	Ite m C	tem Code (Source) N			NDC:41163-111		
Route of Administration	ORAL							
Active Ingredient/Active Ingre	ctive Moiety							
Ingredient Name Basis of Streng					ngth	Strengt		
SODIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74) (PHO SPHATE ION - UNII:NK08V8K8HR)SODIUM PHO SPHATE DIBASIC					Е,	2.7 g in 15 mL		
SODIUM PHO SPHATE, MONOBASIC (UNII: 3980JIH2SW) (PHOSPHATE ION - SODIUM PHOSPHA JNII:NK08V8K8HR) SODIUM PHOSPHA				Е,	7.2 g in 15 mL			
Inactive Ingredients								
Ingredient Name						9	Strength	
GLYCERIN (UNII: PDC6A3								
WATER (UNII: 059QF0KO								
SACCHARIN SO DIUM DIHYDRATE (UNII: SB8ZUX40TY)								
SODIUM BENZOATE (UN	n. 05245FE5E0)							
Packaging								
# Item Code	Package Description	Marketing	g Start	Date	Mai	keting	End Date	
1 NDC:41163-111-12	1 in 1 CARTON							
1	45 mL in 1 BOTTLE							
Marketing Inform	mation							
Marketing Category	Application Number or Monog	graph Citation	Mar	keting Star	rt Date	Market	ing End Dat	
OTC monograph not final	part334		07/16	/2012				

Labeler - SuperValu, Inc. (006961411)

Revised: 8/2012

SuperValu, Inc.