ORAL SALINE LAXATIVE GINGER LEMON- dibasic sodium phosphate, monobasic sodium phosphate liquid

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.

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



sunmark

NDC 49348-111-12

Oral Saline Laxative

Sugar Free

For 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, 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. ■

Drug Facts (continued)

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.

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)

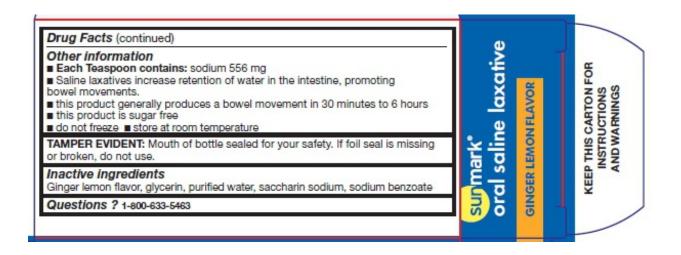
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■ Do not use for bowel cleansing. ■ Do not take more unless directed by a doctor. See Warning. There are three Teaspoons in one Tablespoon.

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ORAL SALINE LAXATIVE GINGER LEMON

dibasic sodium phosphate, monobasic sodium phosphate liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-111	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) (PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, DIBASIC	2.7 g in 15 mL		
SODIUM PHO SPHATE, MONOBASIC (UNII: 3980 JIH2SW) (PHO SPHATE ION - UNII: NK08 V8 K8 HR)	SODIUM PHOSPHATE, MONOBASIC	7.2 g in 15 mL		

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-111-12	1 in 1 CARTON		
1		45 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/31/2012	

Labeler - Mckesson Corporation (177667227)

Revised: 11/2012 Mckesson Corporation