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

Kmart 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. (1-800-222-1222)

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.

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

Questions

1-800-633-5463

Package/Label Principal Display Panel



NDC 49738-111-12

Smart Sense

ORAL SALINE LAXATIVE GINGER LEMON FLAVOR

For relief of occasional constipation Sugar Free 1.5 FL OZ (45 mL)

Package Drug Facts 1

Drug Facts

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. (1-800-222-1222)

Drug Facts (continued)

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.
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Inactive ingredients

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

Questions ? 1-800-633-5463



KEEP THIS CARTON FOI INSTRUCTIONS AND WARNINGS

ORAL SALINE LAXATIVE GINGER LEMON

dibasic sodium phosphate, monobasic sodium phosphate liquid

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:49738-111

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength SODIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74) (PHO SPHATE ION -SODIUM PHOSPHATE, 2.7 g UNII:NK08V8K8HR) DIBASIC in 15 mL $\,$ SODIUM PHO SPHATE, MO NO BASIC (UNII: 3980 JIH2SW) (PHO SPHATE ION -SODIUM PHOSPHATE, 7.2 g UNII:NK08V8K8HR) MONOBASIC in 15 mL

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)			
WATER (UNII: 059QF0KO0R)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:49738-111-12	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 - Kmart Corporation (008965873)

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