ORAL SALINE LAXATIVE LEMON GINGER- sodium phosphate, dibasic and sodium phosphate, monobasic, unspecified form liquid Natureplex, LLC

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.

ORAL SALINE LAXATIVE LEMON GINGER

Drug Facts

| Active ingredients (in each tablespoon) | Purpose |
|---|-----------------|
| Dibasic Sodium Phosphate 2.7g | Saline laxative |
| Monobasic Sodium Phosphate 7.2g | Saline laxative |

Use

- relieves occasional constipation
- this product generally produces bowel movement in 30 minutes to 6 hours

Warnings

Dosage Warning

Taking more than the recommended dosage 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, or uncorrected electrolyte abnormalities
- in children under 6 years old
- for bowel cleansing

Ask a doctor before use if you

- have abdominal pain, nausea, or vomiting
- have kidney disease
- have heart problems
- have a sudden change in bowel habits lasting more than 2 weeks
- have already used a laxative for more than 3 days
- are dehydrated
- are 55 years of age or older
- are on a sodium-restricted diet
- under a doctor's care for any medical condition
- are taking any other prescription or non-prescription medications

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

- you have rectal bleeding
- you do not have a bowel movement within 6 hours
- you have any symptoms that your body is losing more fluid than you are drinking
- you have early symptoms of dehydration including
 - thirstiness
 - 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 right away: 800-222-1222.

Directions (or as directed by a doctor)

- Use as a laxative for relief of occasional constipation
- Dilute dose in the table below with one glass (8 fl oz) of cool water. Drink, then follow with at least one additional glass (8 fl oz) of cool water. There is significant loss of fluid when using this product. To prevent dehydration, drink plenty of clear liquids after use.
- Do not use for bowel cleansing
- There are 3 teaspoons in 1 TABLEspoon
- Do not take more unless directed by a doctor. See Warnings

| Ages (years) | Dosage | Maximum dose |
|--------------|---------------|---------------------------|
| 12 and older | 1 TABLEspoon | 2 to 3 TABLEspoons* |
| 10 to 11 | 1 TABLEspoon* | 1 TABLEspoon [*] |
| 6 to 9 | 1 teaspoons* | 2 teaspoons* |
| Under 6 | ASK A DOCTOR | ASK A DOCTOR |

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

Other information

- each tables poon contains: 1.6 g sodium
- saline laxatives increase retention of water in the intestines, 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 15 to 30°C (59 to 86°F)
- **Tamper Evident:** DO NOT USE IF SEAL ON BOTTLE IS PUNCTURED OR MISSING.

Inactive ingredients

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

Questions or comments?

866-323-0107 or www.natureplex.com

PRINCIPAL DISPLAY PANEL - 45 mL Bottle Carton

B FOR DIRECTIONS LIFT SIDE PANEL

*Natureplex*TM

ORAL SALINE Laxative Phosphate For Relief Of Occasional Constipation

NDC 67234-044-01

Lemon Ginger

1.5 Fl Oz (45 mL)



| Drug Facts (continued) |
|--|
| USe ■ relieves occasional constipation minutes to 6 hours |
| Warnings |
| Do not use ■ if you have a previous kid tunctions, decreased intervascular volum ■ in children under 6 vears old ■ for bov |
| Ask a doctor before use if you ■ have ■have heart problems ■ have a sudden |
| already used a laxative for more than 3 d on a sodium-restricted diet ∎under a do prescription or non-prescription medicatik |
| Ask a doctor or pharmacist before use more hours before or after other drugs. L |
| When using this product a do not use from excess dosage. a do not use for n |
| |
| Drug Facts (continued) |
| Stop use and ask a doctor if a you have arm movement within 6 hours a you have arm you are drinking a you have early sympti e dizziness e urinating less often than no These symptoms may indicate a serious |

| Drug Facts (continued) If pregnant or breast-feeding, ask a he Keep out of reach of children. In case (Poison Control Center right away: 800-25 Poison Control Center right away: 800-26 Poison Control Center right away and Poison Center right away and Poison Control Center right away and Poison Center Poison Center Poison Center right away and Poison Center Poison Center Poison Center Po | one additional glass (8 fl oz) of cool wa product. To prevent dehydration, drink Do not use for bowel cleansing There are 3 teaspoons in 1 TABLEsp Do not take more unless directed by <u>Ages (years)</u> Di <u>12 and older</u> 1 | 10 to 11 1 1 6 to 9 1 1 | Under 6 A. | *SINGLE DAILY DOSAGE. DO NOT TA | |
|---|---|-------------------------|------------|---------------------------------|--|
|---|---|-------------------------|------------|---------------------------------|--|

ORAL SALINE LAXATIVE LEMON GINGER

sodium phosphate, dibasic and sodium phosphate, monobasic, unspecified form liquid

| Product Informa | tion | | | | | | |
|---|--------------|--|--|--------------------|--------------|------------------------|--|
| Product T ype | | HUMAN OTC DRUG | Item Code | NDC:67234-044 | | | |
| Route of Administra | ition | ORAL | | | | | |
| Active Ingredien | t/Active | Moiety | | | | | |
| | I | ngredient Name | | Basis of Strei | ngth Strengt | | |
| SUDILIVIPHUSPHALE DIBASIC LINSPECIFIED FURIVI(LINICURDABLEA/4) | | | SODIUM PHOSPHAT DIBASIC, UNSPECIF FORM | · 140 | | | |
| SODIUM PHOSPHATE, MONOBASIC, UNSPECIFIED FORM (UNII: 3980JIH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37) SODIUM PHOSPHATE MONOBASIC, UNSP | | | | | | 6.2 g in 14.7868 ml | |
| Inactive Ingredients Ingredient Name Strength | | | | | | rength | |
| GLYCERIN (UNII: PDC | C6A3C0OX | • | | Strength | | engen | |
| WATER (UNII: 059QF0K00R) | | | | | | | |
| SACCHARIN SODIUM | I (UNII: SB8 | ZUX40TY) | | | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | | | | | |
| | | | | | | | |
| Product Charact | eristics | | | | | | |
| Color | | | Scor | 'е | | | |
| Shape | | | Size | Size | | | |
| Flavor LEMON, GINGER Imprin | | int Code | | | | | |
| Contains | | | | | | | |
| | | | | | | | |
| Packaging | | | | | | | |
| # Item Code | | Package Description | Ma | rketing Start Date | Market | ing End Date | |
| # Item Code | | | | | | | |
| # Item Code 1 NDC:67234-044-01 | | TON BOTTLE; Type 0: Not a Combination | | 80/2012 | | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC MONOGRAPH NOT FINAL | part334 | 05/30/2012 | | |

| Labeler - | Natureplex, LLC (062808196) |
|-----------|-----------------------------|
|-----------|-----------------------------|

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|------------------------|
| Natureplex LLC | | 062808196 | MANUFACTURE(67234-044) |

Revised: 6/2018

Nature plex, LLC