

MINERAL OIL- mineral oil oil
Harris Teeter, 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.

Drug Facts

Active ingredient

Mineral oil 100%

Purpose

Lubricant laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 6 to 8 hours

Warnings

Do not use

- if you have difficulty swallowing
- in children under 12 years of age
- if you are pregnant
- for a period longer than 1 week
- if you are bedridden or aged
- If you are presently taking a stool softener laxative

Ask a doctor before use if you have

- abdominal pain, nausea, or vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks

When using this product

- do not take with meals
- take only at bedtime

Stop use and ask a doctor if

- you have rectal bleeding or failure to have a bowel movement after use. These could be signs of 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 (1-800-222-1222) right away.

Directions

- do not take with meals
- take only at bedtime
- may be taken as a single daily dose or in divided doses
 - adult and children 12 years of age and over
 - 1 to 3 tablespoons (15 to 45 mL)
 - maximum 3 tablespoons (45 mL) in 24 hours
 - children under 12 years, consult a doctor

Other information

- keep tightly closed
- protect from direct light

Inactive ingredients

Vitamin E as stabilizer

Principal Display Panel**Mineral Oil**

Lubricant laxative

- Odorless
- Tasteless
- Colorless

FL OZ (mL)

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

PROUDLY DISTRIBUTED BY:

HARRIS TEETER, LLC

MATTHEWS, NC 28105

1-800-432-6111 or harristeeter.com

Package Label



Mineral Oil Lubricant laxative

✓ Odorless ✓ Tasteless ✓ Colorless

16 FL OZ (1 PT) 473 mL

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your *plus* guarantee.
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PLD-E280B LB003471

Harris Teeter Mineral Oil

MINERAL OIL

mineral oil oil

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69256-334 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP) | MINERAL OIL | 100 mg in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------|----------|
| TOCOPHEROL (UNII: R0ZB2556P8) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|------------------------------|---------------------------|---|-----------------------------|---------------------------|
| 1 | NDC:69256-334-16 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 01/31/2016 | 12/31/2020 |
| Marketing Information | | | | |
| | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| | OTC MONOGRAPH NOT FINAL | part334 | 01/31/2016 | 12/31/2020 |

Labeler - Harris Teeter, LLC (048463103)

Revised: 11/2019

Harris Teeter, LLC