

MINERAL OIL- mineral oil oil
TOP CARE (Topco Associates 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

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

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
- adults 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 Ingredient

Vitamin E as stabilizer

Principal Display Panel

Mineral Oil

LUBRICANT LAXATIVE

- For Relief of Occasional Constipation
- Odorless
- Tasteless
- Colorless

FL OZ (mL)

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

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

topcare@topco.com

www.topcarebrand.com

Questions or comments? Call toll free 1-888-423-0139

Package Label

NDC:36800-334-16



Mineral Oil

LUBRICANT LAXATIVE

- For Relief of Occasional Constipation
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PLD-F2808 LB005159



0 36800 24712 3

16 FL OZ (1 PT) 473 mL

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PLD-F2808
 LB003471

TOPCARE HEALTH Mineral Oil

MINERAL OIL

mineral oil oil

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:36800-334 |
| Route of Administration | ORAL, TOPICAL | | |

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

Marketing Start Marketing End

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|------------------------------|--|--|----------------------|--------------------|
| 1 | NDC:36800-334-16 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/30/2016 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part334 | 11/30/2016 | | |

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 12/2022

TOP CARE (Topco Associates LLC)