

MINERAL OIL- mineral oil liquid
Retail Business Services

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.

Mineral Oil USP
831.000/831AA

Active ingredient

Mineral oil 99.9%

Purpose

Lubricant laxative

Use

for relief of occasional constipation (irregularity). Generally produces bowel movement in 6 to 8 hours.

Do not use

- if you have difficulty swallowing
- in children under 6 years of age
- if you are pregnant
- for a period longer than 1 week
- if you are bedridden or aged

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

Ask a doctor or pharmacist before use if you are

- presently taking a stool softener laxative
- taking any other drug. Take this product 2 or more hours before or after other drugs. Laxatives may affect how other drugs work

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 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.

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 - 45 mL)
maximum 3 Tablespoons (45 mL) in 24 hours

children 6 to under 12 years of age - 1 to 3 teaspoons (5 - 15 mL) maximum 3
teaspoons (15 mL) in 24 hours

children under 6 years of age - do not use, consult a doctor

Other information

keep tightly closed. Protect from sunlight.

Inactive ingredients

mixed tocopherols (added as a stabilizer)

Questions

Questions? Call 1-877-846-9949

DISTRIBUTED BY: FOODHOLD U.S.A., LLC, LANDOVER, MD 20785

For product questions or concerns, contact us at 1-877-846-9949

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principal display panel

CAREONE

MINERAL OIL

USP

Lubricant Laxative

For relief of occasional constipation

ODORLESS - TASTELESS - COLORLESS

MADE IN THE USE WITH US AND FOREIGN COMPONENTS

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION

OUR PHARMACISTS RECOMMEND

16 FL OZ (1 PT) 473 mL



MINERAL OIL

mineral oil liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:72476-877 |
| 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 | 999 mg in 1 mL |

Inactive Ingredients

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:72476-877-43 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/09/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part334 | 07/09/2018 | |

Labeler - Retail Business Services (967989935)

Registrant - Vi-Jon, LLC (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 790752542 | manufacture(72476-877) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC | | 088520668 | manufacture(72476-877) |

Revised: 9/2022

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