MINERAL OIL- mineral oil liquid CVS Pharmacy

CVS Mineral Oil 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.

Warnings

for thsi product

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

children 6 to under 12 years of age 1 to 3 teaspoons (5 to 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)

Adverse reaction

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woodsocket, RI 02895

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CVS Health ®

Mineral Oil USP

LUBRICANT LAXATIVE

- Odorless
- Tasteless
- Colorless



MINERAL OIL

mineral oil liquid

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51316-831 | |
| Route of Administration | ORAL | | | |

| 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:51316- 831-43 | 473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/16/2024 | |
| 2 | NDC:51316- 831-45 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/16/2024 | |
| | | | | |

| Marketing Information | | | |
|-----------------------|---|-------------------------|-----------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M007 | 02/16/2024 | |
| | | | |

Labeler - CVS Pharmacy (062312574)

Registrant - Consumer Product Partners, LLC (119091520)

| Establishment | | | | |
|--------------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Consumer Product Partners, LLC | | 119091514 | manufacture(51316-831) | |

Revised: 2/2024 CVS Pharmacy