# MINERAL OIL- mineral oil liquid C.D.M.A.

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Quality Choice 831.000/831AA Mineral Oil

### **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 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)

#### Adverse reaction

Distributed by C.D.M.A., Inc.

43157 W 9 Mile Rd,

Novi, MI 48375

www.qualitychoice.com

Questions: 800-935-2362

## Principal display panel

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION

QC

**QUALITY CHOICE** 

Mineral OII

U.S.P.

Lubricant Laxative

For Relief of Occasional Constipation

Odorless - Tasteless - Colorless

16 FL OZ (473 mL)



#### **MINERAL OIL**

mineral oil liquid

| Product Information     |                |                    |               |  |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:83324-171 |  |
| Route of Administration | ORAL           |                    |               |  |

|   | Active Ingredient/Active Moiety                                |                          |                |
|---|--|--------------------------|----------------|
| l | Ingredient Name  | <b>Basis of Strength</b> | Strength       |
| l | 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<br>Date | Marketing End<br>Date |  |
| 1 NDC:83324-171-                | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 07/02/2024              |                       |  |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC Monograph Drug    | M007  | 07/02/2024              |                       |
|                       |   |                         |                       |

# **Labeler -** C.D.M.A. (011920774)

# **Registrant -** Consumer Product Partners, LLC (119091520)

| Establishment                  |         |           |                            |  |  |
|--------------------------------|---------|-----------|----------------------------|--|--|
| Name                           | Address | ID/FEI    | <b>Business Operations</b> |  |  |
| Consumer Product Partners, LLC |         | 119091514 | manufacture(83324-171)     |  |  |

Revised: 7/2024 C.D.M.A.