

**MINERAL OIL- mineral oil oil**  
**Care One (American Sales Company)**

*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.*

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**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

ODORLESS, TASTELESS, COLORLESS

FL OZ (mL)

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

DISTRIBUTED BY

FOODHOLD U.S.A., LLC

LANDOVER, MD 20785

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Questions or comment?

Call 1-877-753-3935 Monday-Friday 9am-5pm EST

### **Package Label**



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Active ingredient	Purpose
Mineral oil 100%	Lubricant laxative
Uses	
<ul style="list-style-type: none"> <li>relieves occasional constipation (irregularity)</li> <li>generally produces bowel movement in 6 to 8 hours</li> </ul>	
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<p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>in children under 12 years of age, pregnant women, bedridden patients or aged, or if you have difficulty swallowing</li> <li>if you are presently taking a stool softener laxative for longer than 1 week</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>abdominal pain, nausea, or vomiting</li> <li>noticed a sudden change in bowel habits that persists over a period of 2 weeks</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>do not take with meals</li> <li>take only at bedtime</li> </ul> <p><b>Stop use and ask a doctor</b> if you have rectal bleeding or failure to have a bowel movement after use. These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding</b>, ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p>	
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PLD-F280B  
LB003471

## CareOne Mineral Oil

### MINERAL OIL

mineral oil oil

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-334
<b>Route of Administration</b>	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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a	11/30/2016	02/28/2025

334-16	Combination Product	11/30/2016	02/28/2025
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part334	11/30/2016	02/28/2025

**Labeler** - Care One (American Sales Company) (809183973)

Revised: 11/2022

Care One (American Sales Company)