

**MINERAL OIL- mineral oil oil**  
**TOP CARE (Topco Associates LLC)**

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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. As with any drug, if you are nursing a baby, seek the advice of a health professional before using this product

**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: oral dosage is a minimal single dose of 15 mL to a maximum daily dose of 45 mL
- children 6 to under 12 years of age: oral dosage is a minimum single dose of 5 mL to a maximum daily dose of 15 mL
- children under 6 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**

**ITASCA, IL 60143**

**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
- Odorless
- Tasteless
- Colorless

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

PLD-J900A LB010465



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16 FL OZ (1 PT) 473 mL

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

## Drug Facts

Active ingredient	Purpose
Mineral oil 100%	Lubricant laxative

**Uses** ■ relieves occasional constipation (irregularity)  
■ generally produces bowel movement in 6 to 8 hours

**Warnings**  
**Do not use** ■ in children under 6 years of age, pregnant women, bedridden patients or persons with difficulty swallowing  
■ if you are presently taking a stool softener laxative  
■ for a period longer than 1 week unless directed by a doctor

**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. As with any drug, if you are nursing a baby, seek the advice of a health professional before using this product.

**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: oral dosage is a minimal single dose of 15 mL to a maximum daily dose of 45 mL  
■ children 6 to under 12 years of age: oral dosage is a minimum single dose of 5 mL to a maximum daily dose of 15 mL  
■ children under 6 years, consult a doctor

**Other information** ■ keep tightly closed ■ protect from direct light

**Inactive ingredient** Vitamin E as stabilizer

PLD-A900A LB010463

TOPCARE HEALTH Mineral Oil

## MINERAL OIL

mineral oil oil

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-334
<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

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	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M007	11/30/2016		

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

Revised: 4/2025

TOP CARE (Topco Associates LLC)