

MINERAL OIL- mineral oil liquid
Perrigo Direct, Inc.

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
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)

Distributed By: Perrigo Direct, Inc.

Peachtree City, GA 30269

[www. PerrigoDirect.com](http://www.PerrigoDirect.com)

1-888-593-0593

principal display panel

NDC 50804-831-43

GOODSENSE

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION

Mineral Oil USP

Lubricant Laxative

For relief of occasional constipation

ODORLESS TASTELESS COLORLESS

16 FL OZ (1 PT) 473 mL



MINERAL OIL

mineral oil liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50804-831
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:50804-831-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/05/1994	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part334		08/05/1994	

Labeler - Perrigo Direct, Inc. (076059836)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(50804-831)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(50804-831)

Revised: 9/2022

Perrigo Direct, Inc.