

**MINERAL OIL- mineral oil oil**  
**Amazon.Com Services LLC**

*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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**Mineral Oil**  
**831.000\_831AA**

**Active ingredient**

Mineral oil 99.9%

**Purpose**

Lubricant laxative

**Use**

for relief of occasional constipation (irregularity). Generally productes bowel movement in 6 to 8 hours.

**Warnings**

Do not use

- if you have difficulty swallowing
- in children under 6 years of age
- if you are pregnant
- for a period of 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 12 years of age - 1 to 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)

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831.000/831AA

**principal display panel**

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION.

SOLIMO

MINERAL OIL U.S.P.

LUBRICANT LAXATIVE

Odorless tasteless colorless

16 FL OZ (1 PT) 473 mL



## MINERAL OIL

mineral oil oil

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72288-831
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)		MINERAL OIL	1 mg in 1 mL	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
TOCOPHEROL (UNII: R0ZB2556P8)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72288-831-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2018	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	05/01/2018		

**Labeler** - Amazon.Com Services LLC (128990418)

**Registrant** - Vi-Jon, LLC (790752542)

**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72288-831)

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Name	Address	ID/FEI	Business Operations
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Revised: 8/2022

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