MINERAL OIL- mineral oil liquid Strategic Sourcing 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.

Mineral Oil USP 831.000/831AA

Distributed by: McKesson Corp. Via Strategic Services LLC.

Memphis, TN 38141

Money Back Guarantee

www.fosterandthrive.com

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.

Warnings

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 to 45 mL) maximum 3 Tablespoons (45 mL) in 24 hours

children 6 to under 12 years of age - 1 to 3 teaspoons (5 to 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)

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You may report serious side effects to 833-358-6431

Monday to Friday 9:00am to 7:00pm EST

Principal Display Panel

NDC 70677-1110-1

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION

Foster & Thrive

Mineral Oil

LUBRICANT LAXATIVE

Odorless Tasteless Colorless

For Relief of:

• Occasional Constipation

16 FL OZ (1PT) 473 mL



MINERAL OIL

mineral oil liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70677-1110

Route of Administration ORAL

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
l		NDC:70677- 1110-1	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2023	

Marketing Information

Marketing in	Harketing information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part334	04/17/2023				

Labeler - Strategic Sourcing Services LLC (116956644)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(70677-1110)	

Establishment

Name	Address	ID/FEI	Business Operations	
Vi-lon, LLC		088520668	manufacture(70677-1110)	

Revised: 4/2023 Strategic Sourcing Services LLC