MINERAL OIL- mineral oil liquid Kroger Co

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 othr drugs. Laxatives may affect how other drugs work.

When using this product

do not take with meals. Take only at bedtime.

Stop use ad 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)

Questions

Call 1-800-632-6900

Adverse reactions

DISTRIBUTED BY THE KROGER CO CINCINNATI, OH 45202

principal display panel

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION

Kroger

OUR PHARMACIST RECOMMENDED

Mineral Oil

U.S.P.

LUBRICANT

LAXATIVE

For Relief of Occasional

Constipation

Odorless,

Tasteless, Colorless

Made in the USA with

US & Foreign Components

16 FL OZ (1 PT) 473 mL



MINERAL OIL

mineral oil liquid

Product Information	tion
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:30142-831

Route of Administration ORAL, TOPICAL

Active Ingredient/Active Moiety

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	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:30142- 831-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1989		

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
part334	07/15/1989		
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date	

Labeler - Kroger Co (006999528)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(30142-831)	

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(30142-831)

Revised: 3/2022 Kroger Co