PREMIER VALUE- mineral oil Pharmacy Value Alliance 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.

Premier Value 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 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)

Questions?

Call 1-888-593-0593

Adverse Reaction

Distributed by: Pharmacy Value Alliance LLC

407 East Lancaster Avenue, Wayne, PA 19087 www.emersongroup.com

If for any reason you are not satisfied with this product,

please return it to the store where purchased for a full refund.

principal display panel

Premier

Value

Mineral Oil usp

lubricant laxative

odorless - tasteless - colorless

for relief of occasional constipation

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION

16 FL OZ (1PT) 473 mL



PREMIER VALUE

mineral oil

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-831
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)		

ı	Packaging				
	# Ito	em Code	Package Description	Marketing Start Date	Marketing End Date
		C:68016- 1-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/19/2009	

	Marketing Information			
plication Number or Monograph Citation	Marketing Start Date	Marketing End Date		
34	05/19/2009			
•	Citation	Citation Date		

Labeler - Pharmacy Value Alliance LLC (101668460)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(68016-831)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		088520668	manufacture(68016-831)	

Revised: 3/2022 Pharmacy Value Alliance LLC