

MINERAL OIL- mineral oil liquid
CARDINAL HEALTH 110, LLC. DBA LEADER

Leader 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.

Warnings

for this product

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)

Questions?

1-888-593-0593

Adverse reaction

DIST. BY CAH DUBLIn, OH 43017

www.myleader.cm

1-800-200-6313

Principal Display Panel

SEALED WITH PRINTED FOIL UNDER CAP FOR YOUR PROTECTION

LEADER

NDC 70000-0663-1

Mineral Oil

Lubricant Laxative

For relief of occasional constipation

100% Money back Guarantee

Odorless, Tasteless, Colorless

Odorless Tasteless, Colorless

16 FL OZ (1PT) 473 mL



MINERAL OIL

mineral oil liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0663
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
1	NDC:70000-0663-1	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	04/17/2023	

Labeler - CARDINAL HEALTH 110, LLC. DBA LEADER (063997360)

Registrant - Consumer Product Partners, LLC (119091520)

Establishment

Name	Address	ID/FEI	Business Operations
Consumer Product Partners, LLC		119091514	manufacture(70000-0663)

Establishment

Name	Address	ID/FEI	Business Operations
Consumer Product Partners, LLC		119091520	manufacture(70000-0663)

Revised: 2/2024

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