

LEADER MINERAL OIL- mineral oil liquid

Cardinal Health, 110 dba Leader

LEADER Mineral Oil

Mineral Oil

Lubricant Laxative

For relief of occasional constipation or irregularity. Generally produces bowel movement in 6 to 8 hours.

Do not use if you have difficulty swallowing, in children under 12 years of age, if you are pregnant, for a period longer than 1 week, if you are bedridden or aged, if you are presently taking a stool softener laxative

Ask a doctor before usage if you have abdominal pain, nausea, or vomiting, noticed a sudden change in bowel habits that persists over a period of 2 weeks.

In case of accidental overdose, seek professional assistance or contact Poison Control Center immediately. In case of eye contact wash gently with water for 15 minutes.

and consult a doctor if there is a failure to have a bowel movement after use.

Adults and children 12 yrs and older: 1 to 2 tablespoonfuls at bedtime.

Children 6 to 12 yrs of age: 1 to 3 teaspoonfuls at bedtime.

Children under 6 yrs of age: Consult a doctor before use

d-alpha-tocopherol as a preservative

Keep tightly closed and protected from direct light



LEADER MINERAL OIL

mineral oil liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0448
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	1000 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0448-1	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	12/18/2018	

Labeler - Cardinal Health, 110 dba Leader (063997360)

Registrant - Pharma Nobis, LLC (118564114)

Establishment

Name	Address	ID/FEI	Business Operations
Pharma Nobis, LLC		118564114	analysis(70000-0448) , manufacture(70000-0448) , pack(70000-0448) , label(70000-0448)

Revised: 12/2023

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