

MINERAL OIL LIGHT, N.F- mineral oil oil
GERITREX 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

Active Ingredient:

Mineral Oil 100%

Use:

Helps treat and prevent diaper rash, protects chafed skin and seals out wetness.

Protects skin.

Keep out of reach of children

⚠Caution: For External Use Only

⚠In case of accidental ingestion seek professional assistance or contact a Poison Control Center immediately. Avoid contact with eyes. In case of accidental eye contact flush eyes gently with water for 15 minutes. Obtain medical attention if irritation persists. If diaper rash worsens or does not improve consult a physician

Clean area thoroughly and allow to dry. Apply mineral oil liberally and as often as needed. Protects the skin against wetness.

Contains:

dl-alpha-tocopherol as preservative. Keep tightly closed and protect from direct sunlight.

Store at room temperature 15-30°C (59-86°F)

54162-190-16



Mineral Oil[™]

U.S.P

LUBRICANT LAXATIVE

ODORLESS • TASTELESS • COLORLESS

16 FL. OZ. (472mL)

Drug Facts

Active Ingredients Purpose

Mineral oil 99.9% 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 one 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 persist 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 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 over 12 years of age	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	Do not use, consult a doctor

Other Information

Keep tightly closed. Protect from sunlight. For more info call 800-736-3437.

Inactive Ingredients

mixed tocopherols (added as a stabilizer)

Geritrex
 144 Kingsbridge Road East
 Mount Vernon, NY 10550
 1-800-736-3437
 www.geritrex.com



mineral oil oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-185
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	471.99 g in 472 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	0.00472 g in 472 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-185-16	472 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/31/2015	

Labeler - GERITREX LLC (112796248)

Registrant - GERITREX LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
GERITREX LLC		112796248	manufacture(54162-185)

Revised: 8/2017

GERITREX LLC