

MINERAL OIL- 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 99.99%

Purpose:

Lubricant Laxative

Uses

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 persists over a period of 2 weeks

Ask a doctor of 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 pregnant or breast feeding,

ask a health professional before use.

Keep out of the reach of children

In case of accidental 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

Age	Dose
adults and children over 12 years	1 to 3 tablespoons (15 to 45 ml) maximum 3 tablespoons (45mL) in 24 hours
children 6 years to under 12 years	1 to 3 teaspoons(15 to 45 ml) maximum 3 teaspoons (45mL) 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)

Principal Display Panel

Geritrex

Mineral Oil

USP

Lubricant Laxative

Odorless

Tasteless

Colorless

16 OZ (472 ml)



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 Corporation
 144 Kingsbridge Road East
 Mount Vernon, NY 10550
 1-800-736-3437
 www.geritrex.com B11



Geritrex®



MINERAL OIL

mineral oil oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-190
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)		MINERAL OIL	471.9528 g in 472 mL	
Inactive Ingredients				
Ingredient Name				Strength
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-190-16	472 mL in 1 BOTTLE, PLASTIC; 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 not final		part334	07/31/2015	

Labeler - Geritrex LLC (112796248)

Registrant - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	repack(54162-190)

Establishment

Name	Address	ID/FEI	Business Operations
Calumet Penreco LLC		114222776	manufacture(54162-190)