

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 Enema

Active Ingredient: **Purpose:**
Mineral Oil USP 100 %.....Lubricant Laxative

Uses:

For relief of fecal impaction or occasional constipation, without straining or irritating the mucosa of the bowel, by lubricating and softening the stool. Generally produces bowel movement in 2 to 15 minutes.

Professional Use:

For cleansing the bowel and removal of residue after barium enema administration

Dosage warning: Using more than one enema in 24 hours can be harmful

Caution: For rectal use only

Ask a doctor before using laxative if you:

- Have nausea, vomiting, or abdominal pain
- Have sudden change in bowel habits lasting more than two weeks
- Have already used a laxative for more than 1 week

Ask a doctor of pharmacist before use if you are taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

When using this product, do not use more than directed.

Serious side effects may occur from excess dosage.

Stop using this product and consult a doctor if you:

- Have rectal bleeding
- Have no bowel movement after the enema is given

These symptoms may indicate a serious condition.

If pregnant or breastfeeding **Ask a health professional before use.**

KEEP OUT OF REACH OF CHILDREN

In the case of accidental ingestion contact a Poison Control Center right away

Remove orange protective shield before inserting by holding bottle upright, grasping bottle cap with fingers. Grasp protective shield with other hand and pull gently to remove, then insert lubricated tip into rectum and squeeze gently.

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

54162-175-05



Mineral Oil Enema

Lubricant Laxative

For relief of occasional constipation

Sodium & Latex Free

Soft lubricated tip

NET WT. 4.5 fl. oz

Drug Facts

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Distributed by Geritrex, LLC
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Mount Vernon, New York 10550
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www.geritrex.com



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Lubricant Laxative

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Oil Enema

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MINERAL OIL

mineral oil oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-175
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	100 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
VITAMIN D (UNII: 9VU1KI44GP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-175-05	113 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	07/31/2015	
2	NDC:54162-175-12	113 g in 1 BOTTLE, WITH APPLICATOR; 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(54162-175)

Establishment

Name	Address	ID/FEI	Business Operations
Calumet Penreco LLC		114222776	manufacture(54162-175)

Revised: 8/2017

GERITREX LLC