

**PURE AND GENTLE- mineral oil enema**  
**Medline Industries, LP**

*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.*

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**013 Pure & Gentle Mineral Oil Enema**

***Active ingredient***  
**(in each 120 mL delivered dose)**

Mineral oil 100% w/v

***Purpose***

Lubricant laxative

***Uses***

- for relief of occasional constipation
- this product generally produces bowel movement in 2 to 15 minutes

***Warnings***

**For rectal use only**

**Caution: to be taken only at bedtime. Do not use at any other time or administer to infants, except upon the advice of a physician.**

**Do not use**

- on children under 13 years of age
- on pregnant women
- on persons with difficulty swallowing
- on bedridden patients
- if you are presently taking a stool softener laxative
- or take with meals

**Ask a doctor before use if you**

- have already used a laxative for more than 3 days
- have abdominal pain, nausea or vomiting
- have a sudden change in bowel habits that persists over a period of 2 weeks

**Stop use and ask a doctor if**

- you have rectal bleeding
- you have no bowel movement within 30 minutes of enema use

**As with any drug, if you are nursing a baby,**

seek the advice of a health professional before using this product.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

**Directions**  
**(or as directed by a doctor)**

**Rectal enema dosage is 120 mL in a single daily dosage (per 24 hours)**

adults & children 13 years and over	1 bottle
children under 13 years of age	DO NOT USE

**Caution:**

Remove green protective shield before inserting: hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with other hand and pull gently to remove



**Positioning:**

Left-side position: Lie on left side with knee bent and arms at rest.



Knee-chest position: Kneel, then lower head and chest forward until left side of face is resting on surface. Position arms comfortably.



**Administering enema:**

- With steady pressure, gently insert enema tip into rectum with a slight side-to-side movement, with tip pointing toward navel. Insertion may be easier if person receiving enema bears down, as if having a bowel movement. This helps relax the muscles

around the anus.

- Do not force the enema tip into rectum as this can cause injury.
- Squeeze bottle until nearly all liquid is gone. It is not necessary to empty the bottle completely, as it contains more liquid than needed.
- Remove enema tip from rectum. This product generally produces a bowel movement in 2 to 15 minutes.
- Do not retain enema solution in body for longer than 15 minutes.

### ***Other Information***

- store at room temperature 15-30°C (59-86°F)
- **Tamper Evident:** DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.

### ***Inactive ingredient***

none

### ***Questions or comments?***

1-866-323-0107 M-F 8 am to 5 pm

### ***Manufacturing Information***

Manufactured for: Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093

Made in USA

[www.medline.com](http://www.medline.com)

1-800-MEDLINE (633-5463)

REF: CUR095010

V1 RD22NPX

### ***Package Label***



# Mineral Oil Enema



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REF CUR095010



NDC 53329-013-11



# Mineral Oil Enema Lubricant Laxative

Comfortable  
Lubricated Tip

Easy to Insert  
Ready-to-Use  
Not made with  
Natural Rubber Latex

1 - 4.5 fl oz (133 mL)

**Caution:**  
Remove green protective shield before inserting; hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with other hand and pull gently to remove.



**Positioning:**  
Left-side position:  
Lie on left side with knee bent and arms at rest.



**Knee-chest position:**  
Kneel, then lower head and chest forward until left side of face is resting on surface. Position arms comfortably.



- Administering Enema:**
- With steady pressure, gently insert enema tip into rectum with a slight side to side movement, with tip pointing toward navel. Insertion may be easier if person receiving enema bears down, as if having a bowel movement. This helps relax the muscles around the anus.
  - Do not force the enema tip into rectum as this can cause injury.
  - Squeeze bottle until nearly all liquid is gone. It is not necessary to empty the bottle completely, as it contains more liquid than needed.
  - Remove enema tip from rectum. This product generally produces a bowel movement in 2 to 15 minutes.
  - Do not retain enema solution in body for longer than 15 minutes.

**TAMPER RESISTANT: DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.**



# Mineral Oil Enema

<b>Drug Facts</b>	
<b>Active ingredient</b> (in each 120 ml delivered dose) Mineral oil 100%.....	<b>Purpose</b> Lubricant laxative
<b>Use</b> ■ for relief of occasional constipation ■ this product generally produces bowel movement in 2 to 15 minutes	
<b>Warnings</b> For rectal use only. <b>Caution:</b> To be taken only at bedtime. Do not use at any other time or administer to infants, except upon the advice of a physician. <b>Do not use</b> ■ on children under 13 years of age ■ on pregnant women ■ on persons with difficulty swallowing ■ on bedridden patients ■ if you are presently taking a stool softener laxative ■ or take with meals <b>Ask a doctor before use if you</b> ■ have already used a laxative for more than 3 days ■ have abdominal pain, nausea, or vomiting ■ have a sudden change in bowel habits that persist over a period of 2 weeks <b>Stop use and ask a doctor if</b> ■ you have rectal bleeding ■ you have no bowel movement within 30 minutes of enema use <b>As with any drug, if you are nursing a baby,</b> seek the advice of a health professional before using this product. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away: 800-222-1222.	
<b>Directions (or as directed by a doctor)</b> Rectal enema dosage is 120 ml in a single daily dosage (per 24 hours).	
Adults & children 13 years of age and older	1 bottle
Children under 13 years of age	DO NOT USE
<b>Other information</b> ■ Store at 15 to 30°C (59 to 86°F). ■ <b>Tamper Evident: DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.</b>	
<b>Inactive ingredient</b> None	
<b>Questions or comments?</b> 1-866-323-0107 M-F 8 am to 5 pm.	

## PURE AND GENTLE

mineral oil enema

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-013
<b>Route of Administration</b>	RECTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MINERAL OIL</b> (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	100 g in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-013-11	1 in 1 BOX	04/09/2014	
1		133 mL in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	04/09/2014	

**Labeler** - Medline Industries, LP (025460908)

Revised: 9/2022

Medline Industries, LP