

ENEMA- mineral oil enema

Dynarex Corporation

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.

Enema, Mineral Oil

Active Ingredient	Purpose
Mineral Oil, 100%	Lubricant Laxative

Uses:

- Gentle relief of occasional constipation

Warnings:

For rectal use only

As a doctor before use if you have:

- abdominal pain, nausea or vomiting
- notice a sudden change in bowel habits that persists over a period of 2 weeks
- **If pregnant or breast feeding**, ask a health professional before use.

Stop use and ask a doctor if:

- If you have rectal bleeding or failure to have a bowel movement after use of a laxative because this may indicate a serious condition
- you need to use a laxative for more than one week

Keep out of reach of children

Keep out of reach of children

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

Other information:

- Store at room temperature 20 Deg C - 25 Deg C (68 Deg F - 77 Deg F)
- This product produces bowel movement in 2 to 15 minutes

Directions

Single daily dose

Adults and children 12 years and older - 1 bottle

Children 2 to under 12 years - 1/2 bottle

Children under 2 years - Do not use. Consult a physician.

How to use this enema:**REMOVE GREEN PROTECTIVE SHIELD BEFORE INSERTING.**

Hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with the other hand and pull gently to remove.

See image on box

Positioning

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

See image on box

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

See image on box

Administering Enema

- With steady pressure, gently insert enema with tip pointing toward navel.
- Squeeze bottle until recommended dose is expelled (it is not necessary to empty unit completely. Bottle contains more liquid than needed for effective use. A small amount of liquid will remain in bottle after squeezing).
- Remove tip from rectum.
- Stop using if tip is hard to insert. Forcing the tip into the rectum can cause injury (especially if you have hemorrhoids). If enema tip causes rectal bleeding or pain, get immediate medical care.
- Maintain position until urge to evacuate is strong (usually 1 to 5 minutes).
- If no urge is felt after 5 minutes of using, try to empty bowel. Call a doctor promptly if no liquid comes out of the rectum after 30 minutes because dehydration could occur.

Principal Display Panel

Mineral oil enema.jpg

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.



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Manufactured for:
Dynarex Corporation
Orangeburg, NY 10962
www.dynarex.com

Made in India



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1 4.5 fl oz
(133 ml)

NDC # 67777-401-01

Enema
Mineral Oil
Lubricant Laxative
Latex Free



*Soft, Flexible,
Comfortable,
Lubricated Tip*

- **Sodium Free
Lubricant Laxative
for Relief of
Occasional
Constipation**
- **Ready-To-Use**

1 4.5 fl oz
(133 ml)

Enema
Mineral Oil
Lubricant Laxative
Latex Free



*Soft, Flexible,
Comfortable,
Lubricated Tip*

Protective
shield prevents
contamination

Comfortable,
lubricated tip for
ease of insertion

One-way safety
valve controls
flow and
prevents reflux

Easy, soft
squeeze bottle



TAMPER EVIDENT: CARTON SEALED FOR SAFETY.
IF PRINTED SEAL ON BOTTOM OR TOP FLAP IS
BROKEN OR MISSING, DO NOT USE

Drug Facts

Active Ingredients
(in each 118 mL
delivered dose)

Mineral oil USP 100%..... Lubricant laxative

Purpose

Uses

Gentle relief of occasional constipation

Warnings

For rectal use only

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

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

Stop use and ask a doctor if

- you have rectal bleeding or failure to have a
bowel movement after use of a laxative
because this may indicate a serious condition
- you need to use a laxative for more than one
week

If pregnant or breast-feeding, ask a health
professional before use.

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

Directions

Single daily dose

Adults & children 12 years and over	1 bottle
Children 2 to under 12 years	½ bottle
Children under 2 years	Do not use. Consult a physician.

Other Information

- store at room temperature 15°-30°C (59°-86°F)
- this product generally produces bowel
movement in 2 to 15 minutes

MH/DRUGS/KD-214

Reorder No. 4718

Reorder No. 4718

ENEMA

mineral oil enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67777-401
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-401-01	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	08/29/2012	

Labeler - Dynarex Corporation (008124539)**Registrant** - Dynarex Corporation (008124539)

Revised: 2/2015

Dynarex Corporation