

**4718 ENEMA, MINERAL OIL- 4718 enema, mineral oil enema
Dynarex**

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.

4718 Enema, Mineral Oil 67777-430-01

Active Ingredient

Mineral Oil 100%

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.

Do not use

- Laxative products when abdominal pain, nausea or vomiting are present unless directed by a doctor.
- Longer than one week unless directed by a doctor.

Ask a doctor before use if you have

- Noticed a sudden change in bowel habits that persists over a period of two weeks.

Stop use and ask a doctor if

- You have rectal bleeding or fail to have a bowel movement after use.

Keep out of reach of children.

- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years old and older: 1 bottle daily.
- Children from 2 to under 12 years of age: 1/2 bottle once daily.
- Children under 2 years old: Consult a doctor.

Other information

- Store at room temperature.

Questions?

- 1-888-Dynarex

Label

CAUTION: REMOVE ORANGE 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 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.




ENEMA
MINERAL OIL
LUBRICANT LAXATIVE

*Soft, Flexible,
Comfortable,
Lubricated Tip*

ENEMA
MINERAL OIL
LUBRICANT LAXATIVE

*Soft, Flexible,
Comfortable,
Lubricated Tip*

• Sodium Free Lubricant Laxative for Relief of Occasional Constipation

• Ready-To-Use

1

4.5 fl. oz.
(133 mL)



1

4.5 fl. oz.
(133 mL)

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

Drug Facts

| Active Ingredient | Purpose |
|---|--------------------|
| (in each 118-mL delivered dose) Mineral Oil 100% | Lubricant Laxative |

Uses

- For relief of occasional constipation
- This product generally produces bowel movement in 2 to 15 minutes

Warnings

For rectal use only

Do not use

- laxative products when abdominal pain, nausea or vomiting are present unless directed by a doctor
- longer than 1 week unless directed by a doctor

Ask a doctor before use if you have 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 fail to have a bowel movement after use

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

| | |
|---|---|
| Adults and children 12 years old and over | 1 bottle once daily |
| Children from 2 to under 12 years of age | ½ bottle once daily, discard unused portion |
| Children under 2 years old | Consult a doctor |

Other Information

- Store at room temperature

Questions?
1-888-DYNAREX

Reorder No. 4718

Manufactured for: Dynarex Corporation
10 Glenshaw Street • Orangeburg, NY 10962
USA • www.dynarex.com
Made in India

SYMBOL GLOSSARY
For an explanation of symbols used in Dynarex packaging, visit dynarex.com/symbols.php

LOT

Enema, Mineral Oil, 4718

4718 ENEMA, MINERAL OIL

4718 enema, mineral oil enema

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67777-430 |
| Route of Administration | RECTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP) | MINERAL OIL | 133 g in 133 mL |

Product Characteristics

| | | | |
|-----------------|----------|---------------------|--|
| Color | | Score | |
| Shape | FREEFORM | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:67777-430-01 | 48 in 1 CASE | 02/26/2021 | |
| 1 | NDC:67777-430-02 | 1 in 1 BOX | | |
| 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 | 02/26/2021 | |

Labeler - Dynarex (008124539)

Revised: 11/2022

Dynarex