

MINERAL OIL- mineral oil enema
Blossom Pharmaceuticals

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 |

Purpose

- 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.

Indications & Usage

- 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

Dosage & Administration

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.

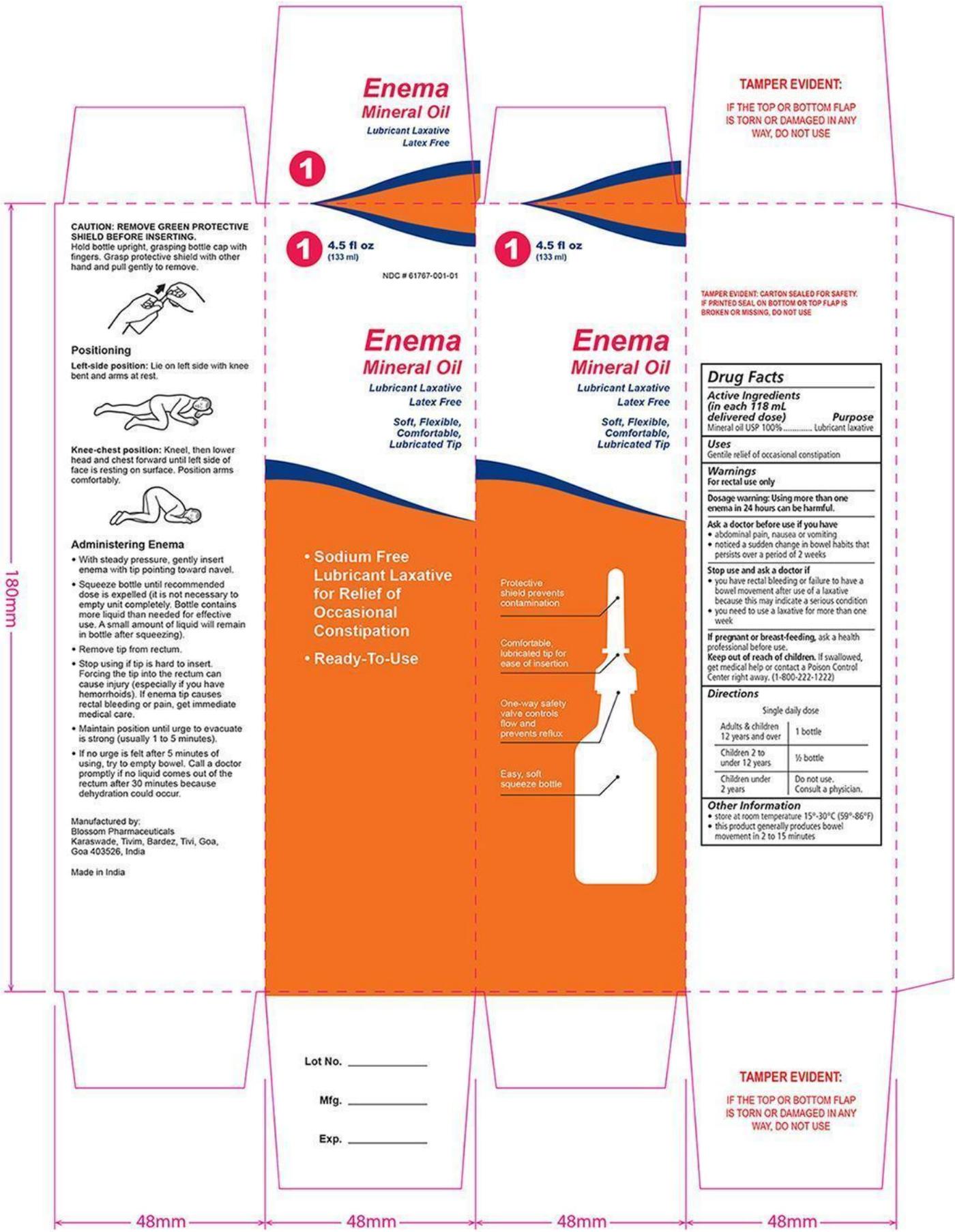
See image on box

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



Enema Mineral Oil

Lubricant Laxative
Latex Free

1

1 4.5 fl oz
(133 ml)

NDC # 61767-001-01

Enema Mineral Oil

Lubricant Laxative
Latex Free

Soft, Flexible,
Comfortable,
Lubricated Tip

Enema Mineral Oil

Lubricant Laxative
Latex Free

Soft, Flexible,
Comfortable,
Lubricated Tip

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



TAMPER EVIDENT:
IF THE TOP OR BOTTOM FLAP
IS TORN OR DAMAGED IN ANY
WAY, DO NOT USE

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 |
| 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 | |
| <ul style="list-style-type: none"> • 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 | |
| <ul style="list-style-type: none"> • 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 | |
| <ul style="list-style-type: none"> • store at room temperature 15°-30°C (59°-86°F) • this product generally produces bowel movement in 2 to 15 minutes | |

TAMPER EVIDENT:
IF THE TOP OR BOTTOM FLAP
IS TORN OR DAMAGED IN ANY
WAY, DO NOT USE

Lot No. _____
Mfg. _____
Exp. _____

180mm

48mm

48mm

48mm

48mm

MINERAL OIL
mineral oil enema

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61767-001 |
| Route of Administration | RECTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|------------------|
| MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP) | MINERAL OIL | 118 mL in 118 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:61767-001-01 | 1 in 1 BOX | | |
| 1 | | 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 | 02/01/2014 | |

Labeler - Blossom Pharmaceuticals (677381470)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|----------------------------|
| Blossom Pharmaceuticals | | 677381470 | manufacture(61767-001) |

Revised: 1/2014

Blossom Pharmaceuticals