SUNMARK MINERAL OIL- mineral oil enema Mckesson 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.

Drug Facts

Active ingredient

(in each 118 mL delivered dose)

Mineral oil 100%

Purpose

Lubricant laxative

Uses

for relief of occasional constipation

Warnings

For rectal use only

Ask 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

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 breastfeeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

Single daily dose

| adults & children | 1 bottle once daily |
|---------------------|------------------------|
| 12 years and over | |
| children 2 to under | 1/2 bottle once daily |
| 12 years | Discard unused portion |
| children under | do not use |

How to use this enema:

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.
- Retain enema in accordance with doctor's instructions.

Other Information

- store at room temperature 20-25 deg C (68-77 deg F)
- this product generally produces bowel movement in 2-15 minutes

Inactive ingredient

none

Questions or comments?

1-800-633-5463

Principal Display Panel

Sunmark

Compare to Fleet® Mineral Oil Enema active ingredient

NDC 49348-880-20

Complete Ready-To-Use

Enema

Mineral Oil

Sodium Free Lubricant

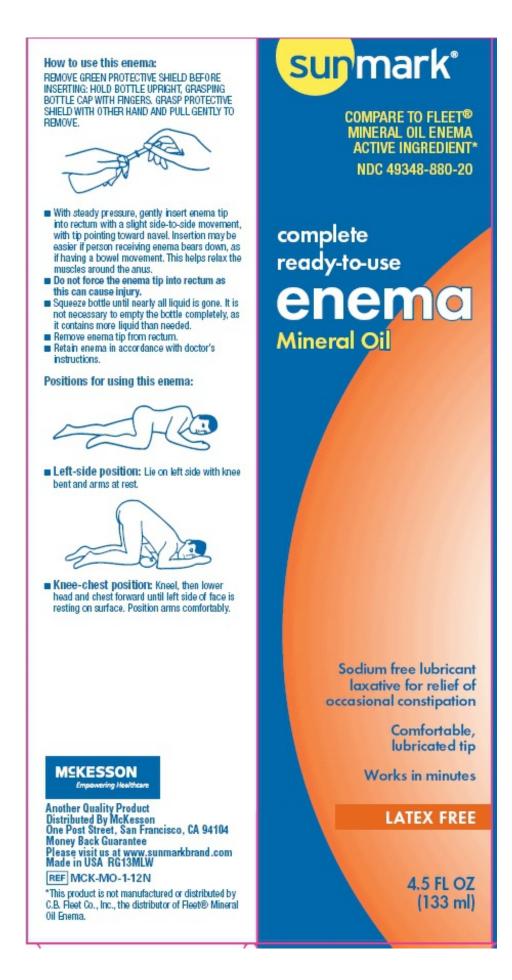
Laxative For Relief

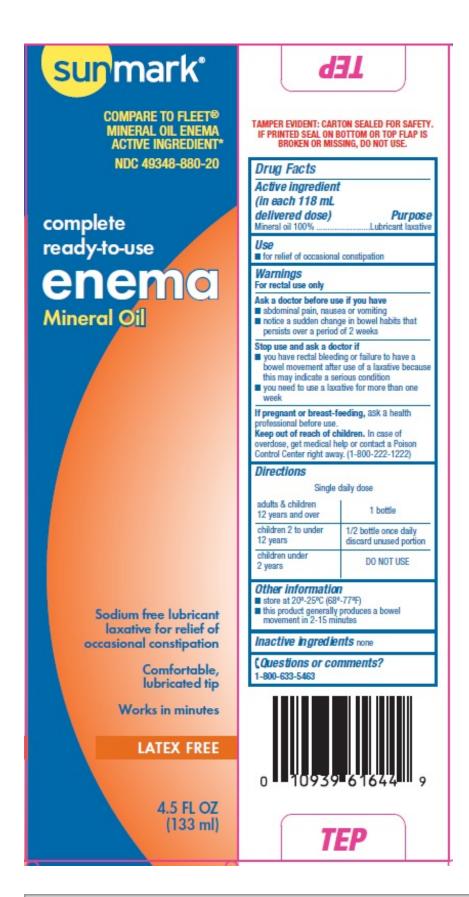
of Occasional Constipation

Comfortable, Lubricated Tip

Latex Free

4.5 FL OZ (133ml)





SUNMARK MINERAL OIL

mineral oil enema

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:49348-880

| 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:49348-880-20 | 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 | 08/01/2013 | | | |
| | | | | | |

Labeler - Mckesson Corporation (177667227)

Revised: 7/2015 Mckesson Corporation