

LEADER MINERAL OIL- mineral oil enema
CARDINAL HEALTH, INC.

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 12 years and over	1 bottle once daily
children 2 to under 12 years	1/2 bottle once daily 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

Leader

Compare to Fleet® Mineral Oil Enema active ingredient

Ready-To-Use

Enema Mineral Oil

Sodium Free Lubricant

Laxative For Relief

of Occasional Constipation

Comfortable, Lubricated Tip

Works In Minutes

Latex Free

Satisfaction Guaranteed

4.5 FL OZ (133ml)

UCN 131
333-000 UCN131-1

TEP

LEADER®

Ready-To-Use

Enema Mineral Oil

NDC 37206-766-11

LEADER®

Compare to Fleet®
Mineral Oil Enema
active ingredient

Ready-To-Use

Enema Mineral Oil

*Sodium Free Lubricant
Laxative For Relief of
Occasional Constipation*

*Comfortable, Lubricated Tip
Works In Minutes*

Latex Free



4.5 FL OZ (133 ml)

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.



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

Positions for using this enema:



- **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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DUBLIN, OHIO 43017
CN 472537
www.myleader.com
1-800-200-6313

Made in USA RK13CTR [TEP] CRD-MO-1-12H

**All Leader® Brand products are
100% satisfaction guaranteed or return
to place of purchase for a full refund.**

*This product is not manufactured or distributed by
C.B. Fleet Co., Inc., the distributor of Fleet® Mineral
Oil Enema.

Side and Back Panel - Box

LEADER®

Compare to Fleet®
Mineral Oil Enema
active ingredient*

Ready-To-Use

Enema Mineral Oil

Sodium Free Lubricant
Laxative For Relief of
Occasional Constipation

Comfortable, Lubricated Tip
Works In Minutes

Latex Free

Protective shield
prevents
contamination

Comfortable,
lubricated tip for
ease of insertion

One-way safety valve
controls flow and
prevents reflux

Easy, soft squeeze
bottle



4.5 FL OZ (133 ml)

TEP

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
(in each 118 mL delivered dose) **Purpose**
Mineral oil 100%Lubricant laxative

Use
■ for relief of occasional constipation

Warnings
For rectal use only

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Stop use and ask a doctor if
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If pregnant or breast-feeding, ASK a health professional before use.
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Directions

Single daily dose

adults & children 12 years and over	1 bottle
children 2 to under 12 years	1/2 bottle once daily discard unused portion
children under 2 years	DO NOT USE

Other information
■ store at controlled room temperature
■ this product generally produces a bowel movement in 2-15 minutes

Inactive ingredients none

Questions or comments?
1-800-633-5463



TEP

LEADER MINERAL OIL

mineral oil enema

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:37205-755

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:37205-755-11	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	02/19/2013	

Labeler - CARDINAL HEALTH, INC. (097537435)

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CARDINAL HEALTH, INC.