

LEADER READY TO USE MINERAL OIL LAXATIVE- mineral oil enema

Cardinal Health

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.

Leader[®] Ready to Use Mineral Oil Enema

Laxative

Drug Facts

Active ingredient (in each 118 mL delivered dose)

Mineral oil 100%

Purpose

Lubricant laxative

Uses

- for relief of occasional constipation
- for relief of fecal impaction
- for removal of residue after barium administration

Warnings

For rectal use only

Ask a doctor before use

- if you have abdominal pain, nausea, or vomiting
- if you have a sudden change in bowel habits that persists over a period of 2 weeks
- if you have already used a laxative for more than 1 week
- if constipation continues after one week of use, contact your doctor

Stop use and ask a doctor if

- you have rectal bleeding or no bowel movement within 15 minutes of using this product
- you need to use a laxative for more than one week

These symptoms may indicate a serious condition.

If pregnant or breastfeeding, ask a health professional before use.

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

Directions

Single daily dose (per 24 hours).

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 2 years	DO NOT USE

Other information

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

Inactive ingredients

none

Questions or comments?

1-866-323-0107

**DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017**

PRINCIPAL DISPLAY PANEL - 133 mL Bottle Carton

LEADER™

NDC 70000-0109-1

Ready-To-Use

Enema

Mineral Oil

Lubricant Laxative

Sodium Free

For Relief Of:

Occasional
Constipation

Comfortable,
Lubricated Tip

Works in
Minutes

Not Made

With Natural
Rubber
Latex

COMPARE TO
FLEET® MINERAL
OIL ENEMA
active ingredient*

1 BOTTLE

100% Money
Back Guarantee

4 .5 FL OZ (133 mL)

LEADER[?]

Ready-To-Use
Enema
Mineral Oil
Lubricant Laxative

PL313023
V02

Positions for using this enema

Left-side position: Lie on left side with knees bent and arms resting comfortably.



Knee-chest position: Kneel, then lower head and chest forward until left side of face is resting on surface with left arm folded comfortably.



How to use this enema

- Remove protective shield from enema tip before inserting. Hold bottle upright, grasping bottle cap with fingers. Grasp protective shield with other hand and pull gently to remove.



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. Doing so helps relax muscles around anus.
- Do not force enema tip into 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.
- Squeeze bottle until nearly all liquid is gone. It is not necessary to empty bottle completely, as it contains more liquid than needed.
- Remove tip from rectum and stay in position until urge to evacuate is strong (usually 2 to 15 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.

CIN 5205539 REV. 5/18
RC15CTR REF CRD-MO-1-12N



NDC70000-0109-1

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4.5 FL. OZ. (133 mL)

LEADER[?]

Ready-To-Use
Enema
Mineral Oil
Lubricant Laxative



Protective shield
prevents
contamination

Comfortable,
lubricated tip for
ease of insertion

One-way safety valve
controls flow and
prevents reflux

Easy, soft squeeze
bottle



DISTRIBUTED BY CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Essential to Care[™] since 1979

100%
Money Back
Guarantee

Return to place of purchase.

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 120 mL delivered dose)
Mineral oil 100%.....Lubricant laxative

Use

- for relief of occasional constipation
- this product generally produces bowel movement in 2 to 15 minutes

Warnings

For rectal use only.

Caution: To be taken only at bedtime. Do not use at any other time or administer to infants, except upon the advice of a physician.

Do not use ■ on children under 13 years of age ■ on pregnant women ■ on persons with difficulty swallowing ■ on bedridden patients ■ if you are presently taking a stool softener laxative ■ or take with meals

Ask a doctor before use if you ■ have already used a laxative for more than 3 days ■ have abdominal pain, nausea, or vomiting ■ have a sudden change in bowel habits that persist over a period of 2 weeks

Stop use and ask a doctor if ■ you have rectal bleeding ■ you have no bowel movement within 30 minutes of enema use

As with any drug, if you are nursing a baby, seek the advice of a health professional before using this product.

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

Directions (or as directed by a doctor)
Rectal enema dosage is 120 ml in a single daily dosage (per 24 hours).

Adults & children 13 years of age and older	1 bottle
Children under 13 years of age	DO NOT USE

Other information

- Store at 15 to 30°C (59 to 86°F).
- Tamper Evident: DO NOT USE IF TOP OR BOTTOM FLAP OF CARTON IS TORN OR MISSING.

Inactive ingredient

None

Questions or comments?

866-323-0107 or www.natureplex.com

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LEADER READY TO USE MINERAL OIL LAXATIVE

mineral oil enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0109
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 g in 118 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0109-1	1 in 1 CARTON	02/19/2013	
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 (063997360)

Establishment

Name	Address	ID/FEI	Business Operations
Natureplex LLC		062808196	MANUFACTURE(70000-0109)

Revised: 6/2021

Cardinal Health