

MINERAL OIL- mineral oil enema
Galentic Pharma (India) Private Limited

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

Uses:

- 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.

Stop use and ask a doctor if:

- 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

Directions

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

Galentic Mineral Oil Enema

Gal Enema Min Oil.jpg

CAUTION: REMOVE GREEN PROTECTIVE SHIELD BEFORE INSERTING.
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Positioning

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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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Manufactured for:
Galentic Pharma India
Private Limited
Navi Mumbai,
Maharashtra 400701
Made in India

1 4.5 fl oz
(133 ml)

NDC # 50382-001-01

**Galentic
Enema
Mineral Oil**

Lubricant Laxative
Latex Free

Soft, Flexible,
Comfortable,
Lubricated Tip

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

1 4.5 fl oz
(133 ml)

**Galentic
Enema
Mineral Oil**

Lubricant Laxative
Latex Free

Soft, Flexible,
Comfortable,
Lubricated Tip

Protective shield prevents contamination

Comfortable, lubricated tip for ease of insertion

One-way safety valve controls flow and prevents reflux

Easy, soft squeeze bottle



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)

Ingredient	Purpose
Mineral oil USP 100%	Lubricant laxative

Uses
Gentile 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

- 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

- 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

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

MH/DRUGS/KD-214

Reorder No. 4718

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MINERAL OIL

mineral oil enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50382-009
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:50382-009-01	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	08/07/2013	

Labeler - Galentic Pharma (India) Private Limited (918531450)**Establishment**

Name	Address	ID/FEI	Business Operations
Galentic Pharma (India) Private Limited		918531450	manufacture(50382-009)

Revised: 8/2013

Galentic Pharma (India) Private Limited