# FLEET- mineral oil enema C.B. Fleet Company, 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.

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#### Fleet Mineral Oil

### **Drug Facts**

### Active ingredient (in each 118 mL delivered dose)

Mineral oil 100%

### **Purpose**

Lubricant laxative

#### Uses

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

This product usually produces a bowel movement in 2 to 15 minutes.

### Warnings

### For rectal use only

#### Do not use

when abdominal pain, nausea, or vomiting are present unless directed by a doctor

### Ask a doctor before using this product if you

- have a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more than 1 week

### Stop use and ask a doctor if you have

- rectal bleeding
- no bowel movement within 15 minutes of using this product

These symptoms may indicate a serious condition.

### 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.

#### Directions

## Single Daily Dosage (per 24 hours)

	adults and children	1 bottle per day	
	12 years and over	bottae per day	
	children	one-half bottle	
_	2 to under 12 years	one-nam boure	
	children	DO NOT USE	
	under 2 years	DO NOT USE	

## Other information

- sodium-free
- for complete Professional Use, Warnings and Precautions, consult the Reference Safety Information on our website

### Questions?

1-866-255-6960 or www.fleetlabs.com

### PRINCIPAL DISPLAY PANEL

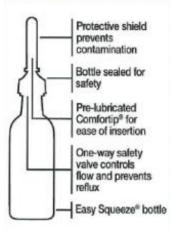
### Fleet<sub>®</sub>

Mineral Oil enema

lubricant laxative

1 bottle - 4.5 FL OZ (133 mL)

### Complete enema in a disposable squeeze bottle with soft, pre-lubricated Comfortip®



Fleet® Enemas are LATEX-FREE,

Mid. by C.B. Fleet Company, Inc., Lynchburg, VA 24502 USA FILISDIMION

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#### How to use this enema:

MOVE GREEN WRAPPER WITH PLEET MELEM AND GRANGE PROTECTIVE HELD FROM ENEMA COMFORTIP



- 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.
- 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 Comfortip® from rectum and maintain position until urge to evacuate is strong (usually 2 to 15 minutes).
- Do not retain enema solution for more than 15 minutes.
- If constipation continues after one week of use, contact your doctor.

#### Positions for using this enema:



■ Left-side position: Lie on left side with knee 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.

\*Based on laboratory data





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- a for relief of fecal impaction
- for relief of occasional constipation
- for removal of residue after barium administration
- This product usually produces a bowel movement in 2 to 15 minutes

#### Warnings

For rectal use only

Do not use when abdominal pain, nausea, or vomiting are present unless directed by a doctor

#### Ask a doctor before using this product if you

- have a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more

#### Stop use and ask a doctor if you have ■ rectal bleeding

 no bowel movement within 15 minutes of using this product These symptoms may indicate a serious condition.

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.

#### Directions

Single Daily Dosage (per 24 hours).

adults and children 12 years and over	1 bottle per day
children 2 to 12 years	one-half bottle
children under 2 years	DO NOT USE

#### Other information

sodium-free

for complete Professional Use, Warnings and Precautions, consult the Reference Safety Information on our website

Questions? 1-866-255-6960 or www.fleetlabs.com

Tamper Evident: bottle sealed for safety. If bottle wrapper with Fleet\* emblem is torn, damaged or missing, do not use.

#### FLEET

mineral oil enema

#### **Product Information**

HUMAN OTC DRUG NDC:0132-0301 Product Type Item Code (Source)

Route of Administration RECTAL

### Active Ingredient/Active Moiety

l	Ingredient Name	Basis of Strength	Strength
ı	MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	100 g in 100 mL

l	Packaging	ackaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date			
	1 NDC:0132-0301	- 133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/01/2002				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	05/01/2002	

## Labeler - C.B. Fleet Company, Inc. (003119054)

Revised: 1/2021 C.B. Fleet Company, Inc.