

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.

Drug Facts

Active Ingredient

(in each 118-mL delivered dose)

Mineral Oil 100%Lubricant Laxative

Uses

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

Warnings

For rectal use only.

If pregnant or breast-feeding ask a health professional before use.

Directions

Single daily dose

adults and children 12 years and over	1 bottle
children 2 to under 12 years	one-half bottle
children under 2 years	<u>DO NOT USE</u>

Other Information

Other Information

- sodium free
- this product generally produces a bowel movement in 2-15 minutes
- carton sealed for safety. If seal with Fleet emblem on top or bottom flap is missing, do not use
- consult Physicians' Desk Reference for complete professional labeling

Questions?

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

Ask a doctor before using any laxative if you have

- abdominal pain, nausea or vomiting
- 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 after use

These symptoms may indicate a serious condition.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.



MINERAL OIL
enema

ready-to-use

soft, flexible
Comfortip®

latex-free

sodium-free

#1 DOCTOR
RECOMMENDED
LAXATIVE BRAND

1 Bottle
4.5 Fl Oz (133 ml)

FLEET

mineral oil enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0301
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:0132-0301-40	133 mL in 1 BOTTLE, WITH APPLICATOR		

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)**Establishment**

Name	Address	ID/FEI	Business Operations
C.B. Fleet Company, Inc.		003119054	manufacture(0132-0301)

Revised: 2/2013

C.B. Fleet Company, Inc.