

FLEET- enema 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)

Monobasic Sodium Phosphate 19 g, Saline Laxative
Dibasic Sodium Phosphate 7 g, Saline Laxative

Use

For relief of occasional constipation

Warnings

For rectal use only.

Dosage warning:

Using more than one enema in 24 hours can be harmful. Do not use without asking a doctor:

- for more than 3 days
- if you have kidney disease
- if you have heart problems
- if you are dehydrated

Ask a doctor before using this product if you

- are 55 years or older
- are on a sodium-restricted diet

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 or no liquid comes out of the rectum after 30 minutes
- symptoms of dehydration (feeling thirsty, dizziness, vomiting or urinating less often than normal)

These symptoms may indicate a serious condition

If pregnant or breast-feeding

Ask a health professional before use.

Keep out of reach of children**Keep out of reach of children to prevent accidental ingestion.**

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

Directions

Single Daily Dosage (per 24 hours).

Do not use more unless directed by a doctor. See Warnings.

Do not use if taking another sodium phosphates product.

adults and children 12 years and over	1 bottle per day
children 2 to 11 years	Use Fleet Pedia-Lax Enema
children under 2 years	DO NOT USE

Other Information

- each 118-mL delivered dose contains: sodium 4.4 g
- additional liquids by mouth are recommended while taking this product
- this product generally produces a bowel movement in 1-5 minutes
- BOTTLE SEALED FOR SAFETY. IF BOTTLE WRAPPER WITH FLEET EMBLEM IS TORN, DAMAGED OR MISSING, DO NOT USE.
- for complete professional use warnings and precautions, consult the Reference Safety Information on our website

Inactive Ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions?

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

GOES STRAIGHT TO THE PROBLEM FOR THE

FASTEST RELIEF

Fleet

NDC 0132-0119-40

laxative

SALINE
enema

SIX PACK

- ✓ ready-to-use
- ✓ soft, flexible Comfortip®
- ✓ latex-free
- ✓ Easy Squeeze® bottle

#1 DOCTOR
RECOMMENDED
ENEMA BRAND

6 Bottles
4.5 FL Oz (133 mL) each

FLEET

enema enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0119
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980J1H2SW) (SODIUM CATION - UNII:L YR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC	19 g in 133 mL
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74) (SODIUM CATION - UNII:L YR4M0NH37)	SODIUM PHOSPHATE, DIBASIC	7 g in 133 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:0132-0119-46	133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/26/2011	
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/26/2011	

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

Establishment

Name	Address	ID/FEI	Business Operations
C.B. Fleet Company, Inc.		003119054	manufacture(0132-0119)

Revised: 8/2017

C.B. Fleet Company, Inc.