

FLEET- sodium phosphate, dibasic and sodium phosphate, monobasic 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.

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 of age 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 consult 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.

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.

If pregnant or breast-feeding

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

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.

Other Information

- each 118-mL delivered dose contains: sodium 4.4 g
- additional liquids by mouth are recommended while taking this product
- this product usually 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 Reference Safety Information on our website

Inactive Ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions?

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

Fleet Enema Principle Display Panel

GOES STRAIGHT TO THE
PROBLEM FOR THE

**FASTEST
RELIEF**

Fleet[®]

laxative

SALINE
enema

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

**#1 DOCTOR
RECOMMENDED
ENEMA BRAND**

1 Bottle
4.5 Fl Oz (133 mL)

FLEET

sodium phosphate, dibasic and sodium phosphate, monobasic enema

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0201
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	7 g in 133 mL
sodium phosphate, monobasic (UNII: 3980JH2SW) (PHOSPHATE ION - UNII:NK08V8K8HR, SODIUM CATION - UNII:LYR4M0NH37)	sodium phosphate, monobasic	19 g in 133 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0201-40	133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/15/2017	
2	NDC:0132-0201-42	133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/15/2017	
3	NDC:0132-0201-45	133 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	05/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/10/1953	

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

Establishment

Name	Address	ID/FEI	Business Operations
C.B. Fleet Company, Inc.		003119054	manufacture(0132-0201)

Revised: 6/2017

C.B. Fleet Company, Inc.