FLEET- sodium phosphate, dibasic, heptahydrate 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.

Drug Facts

Active Ingredient (in each 197-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.

Using more than one enema in 24 hours can be harmful.

Ask a doctor before using this product if the child

- is on a sodium-restricted diet
- has kidney disease

Ask a doctor before using any laxative if the child has

- 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 the child has

- rectal bleeding
- no bowel movement within 30 minutes of enema use
- 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

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

Directions

Single Daily Dosage

Do not use more unless directed by a doctor. See Warnings. Do not use if child is taking another sodium phosphates product.

children 5 to 11 years	1 bottle or as directed by a doctor	_
children 2 to under 5 years	one-half bottle (see below)	
children under 2 years	DO NOT USE	

One-half bottle prepararation:

Unscrew cap and remove 2 tablespoons of liquid with a measuring spoon. Replace cap and follow directions.

Other Information

- each 197-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
- carton sealed for safety. If seal with Fleet emblem on top or bottom flap is broken or missing, do not use
- for complete professional use warnings and precautions, consult Physicians' Desk Reference

Inactive Ingredients

benzalkonium chloride, disodium EDTA, purified water

Questions?

1-866-255-6960 or www.pedia-lax.com



FLEET

sodium phosphate, dibasic and sodium phosphate, monobasic enema

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

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
$\begin{tabular}{ll} \textbf{SODIUM PHO SPHATE, DIBASIC, HEPTAHYDRATE} (PHOSPHATE ION and SODIUM CATION) \end{tabular}$	SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	7 g in 230 mL	
		10 ~	

Inactive Ingredients	
Ingredient Name	Strength
EDETATE DISO DIUM	
WATER	
RENZALKONIUM CHI ODIDE	

	Packaging			
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:0132-0201-10	230 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	06/25/2004	

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

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

Revised: 2/2013 C.B. Fleet Company, Inc.