

PEDIA-LAX- docusate sodium liquid

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 tablespoon)

Docusate Sodium 50 mg

Uses

- for the prevention of dry, hard stools
- for relief of occasional constipation
- this product generally produces bowel movement in 12-72 hours

Warnings

Drug interaction precaution: do not give this product to your child if your child is presently taking mineral oil unless directed by a doctor.

Ask a doctor before using any laxative if your 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 using this product and consult a doctor if your child has

- rectal bleeding
- no bowel movement within 72 hours of using this product

These symptoms may be signs of a serious condition.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Use dosage chart for proper dosing. Doses may be taken as a single daily dose or in divided doses.

Doses must be given in a 6-8 oz glass of milk or juice, to prevent throat irritation.

Age	Starting Dose	Maximum Dose per Day
children 2 to under 12 years	1 - 3 tablespoons	3 tablespoons
children under 2 years	ask a doctor	

Other Information

- each tablespoon contains: sodium 13 mg
- CHILD RESISTANT CAP
- The top of the bottle is sealed with foil for your safety. Do not use if foil imprinted "SEALED for YOUR PROTECTION" is broken or missing.

Inactive Ingredients

citric acid, edetate disodium, FD and C red 3, flavor, methylparaben, polyethylene glycol, povidone, propylene glycol, propylparaben, sodium citrate, sorbitol, sucralose, water, xanthan gum, xylitol

Questions?

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



PEDIA-LAX

docusate sodium liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0106
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg in 118 mL

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
XYLITOL (UNII: VCQ006KQ1E)	
XANTHAN GUM (UNII: TTV12P4NEE)	

WATER (UNII: 059QF0K00R)
SUCRALOSE (UNII: 96K6UQ3ZD4)
SORBITOL (UNII: 506T60A25R)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
POVIDONE (UNII: FZ989GH94E)
METHYLPARABEN (UNII: A2I8C7H9T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)
POLYETHYLENE GLYCOL 4500 (UNII: TVH7653921)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	FRUIT PUNCH	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0106-24	118 mL in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/01/2008	

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

Establishment

Name	Address	ID/FEI	Business Operations
C.B. Fleet Company, Inc.		003119054	manufacture(0132-0106)