

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.

Pedia-lax Docusate Sodium Liquid 0132-0107

Drug Facts

Active Ingredients

(in each 15 mL)

Docusate Sodium 50 mg

Purpose

Stool softener

Uses

- for prevention of dry, hard stools
- for relief of occasional constipation
- this product usually produces a bowel movement in 12 to 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

- a sudden change in bowel habits lasting more than 2 weeks
- already used a laxative for more than 1 week

If constipation continues after 1 week of use, contact your child's doctor

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 (1-800-222-1222) right away.

Directions

- do not give more than 45 mL in any 24 hour period
- use only with enclosed dosing cup
- find right dose on chart below
- mL = milliliter

Age	Dose
Children 2 to under 12 years	15 mL to 45 mL; do not take more than 45 mL in 24 hours
Children under 2 years	ask a doctor

Doses can be diluted in a suitable beverage to prevent throat irritation and to help mask the naturally tart flavor of the active ingredient (see side panel for info).

Other information

- each 15 mL contains: **sodium 13 mg**
- 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.
- gluten free

Inactive Ingredients

citric acid, edetate disodium, 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

PRINCIPAL DISPLAY PANEL

Pedia-Lax
Docusate sodium
Liquid Stool Softener
4 fl oz (118 mL)



PEDIA-LAX

docusate sodium liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0132-0107
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 15 mL	
Inactive Ingredients				
Ingredient Name		Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
WATER (UNII: 059QF0KO0R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
XYLITOL (UNII: VCQ006KQ1E)				
Product Characteristics				
Color	white (Colorless)	Score		
Shape		Size		
Flavor	BERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0132-0107-24	118 mL in 1 CARTON; Type 0: Not a Combination Product	02/01/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part334	02/01/2020		

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