DOCUSATE SODIUM LIQUID- docusate sodium liquid
ATLANTIC BIOLOGICALS CORP.

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 Ingredients (per 5 mL)

Docusate Sodium 50 mg

Purpose

Stool Softener

Uses

Relief of occasional constipation

Warnings

Do not use when
- abdominal pain, nausea, or vomiting are present unless directed by a doctor
- for more than one week unless directed by a doctor

Ask a doctore before use if you
- are taking mineral oil
- have noticed a sudden change in bowel habits that last more than two weeks

Stop use and ask doctor if
- you have no bowel movements within 3 days
- you have rectal bleeding
- these could be signs of a serious condition
- a skin rash occurs
- you experience throat irritation

If pregnant or breast-feeding, ask a doctor before use

Keep out of reach of children. In case of accidental overdose, seek medical assistance or contact a Poison Control Center right away.

Directions
- follow dosing directions below or use as directed by a physician
- must be given in a 6 oz to 8 oz glass of milk or fruit juice to prevent throat irritation
- may be taken as a single daily dose or in dividend dose
- take maximum dose daily until first bowel movement, dosage should then be reduced according to individual response
- do not exceed recommended dose
- shake well before using

1 teasponnful = 5 mL

Age	Dose
Adults and children over 12 years of age	1 to 6 teaspoons (50 mg - 300 mg)
Children under 12 years of age	Ask a doctor

Inactive ingredients: FD&C red #40, flavor, methylparaben, poloxamer, polyethylene glycol, propylene glycol, propylparaben, sodium benzoate, sodium citrate, sucralose

DISTRIBUTED BY

ATLANTIC BIOLOGICALS CORP

MIAMI, FL 33179

Questions or comments? 1-800-645-2158

DOCUSATE SODIUM LIQUID

docusate sodium liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-1304(NDC:0536-1304)
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 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**

FD&C RED NO. 40 (UNII: WZB9127XOA)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLOXAMER 124 (UNII: 1S66E28KXA)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-1304-1	50 in 1 BOX, UNIT-DOSE	05/22/2023	
1	NDC:17856-1304-3	25 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-1304-2	72 in 1 BOX, UNIT-DOSE	05/22/2023	
2	NDC:17856-1304-4	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/01/2020	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
UNIT DOSE SOLUTIONS		360804194	repack(17856-1304)

Revised: 5/2023 ATLANTIC BIOLOGICALS CORP.