STOOL SOFTENER 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.

GNP DOCUSATE LIQUID

Active ingredient (in each 5 mL teaspoonful)

Docusate Sodium 50 mg

Purpose

Stool Softener Laxative

Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use for more than one week unless directed by a doctor

Ask a doctor before use if you

- have abdominal pain, nausea, or vomiting
- are taking mineral oil
- have noticed a sudden change in bowel habits that lasts more than 14 days

Stop use and ask a doctor if

- you have rectal bleeding or failure to have a bowel movement within 3 days. These could be signs of a serious condition.
- a skin rash occurs
- you experience throat irritation

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

Keep out of reach of children. In case of overdose, get medical help or contact a poison control Center right away.

Directions

- follow dosing directions below or take as directed by doctor
- must be given in a 6 to 8 oz glass of milk or fruit juice to prevent throat irritation
- may be taken as a single daily dose or in divided doses
- take maximum daily dose until first bowel movement, then reduce dose according to individual response
- shake well before using

Adults and children 12 years and over	1 to 4 teaspoonfuls (5 to 20 mL)
Children under 12 years of age	ask a doctor

Other information

- **Each teaspoonful contains:** sodium 15 mg
- Store at room temperature 15°- 30° C (59°-86° F)
- protect from excessive heat
- Keep tightly closed

Inactive ingredients

citric acid, D&C Red #33, flavor, parabens, poloxamer, polyethylene glycol, sodium citrate, sorbitol, sucrose, and water.

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

20101 N.E 16TH PLACE

MIAMI, FL 33179

package label

NDC 17856-0398-1

Compare to Colace® Liquid active ingredient *

GOOD NEIGHBOR PHARMACY

STOOL
SOFTENER
LIQUID
Docusate Sodium
Relieves Constipation
250mg/25 mL

50 cups per case

NDC 17856-0398-2

Compare to Colace® Liquid active ingredient *

GOOD NEIGHBOR PHARMACY

STOOL
SOFTENER
LIQUID
Docusate Sodium
Relieves Constipation
100mg/10 mL

72 cups per case

STOOL SOFTENER LIQUID

docusate sodium liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:17856-0398(NDC:46122-399)
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**

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SUCROSE (UNII: C151H8M554)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	pink	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-0398-1	50 in 1 BOX, UNIT-DOSE	01/18/2021	
1		25 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-0398-2	72 in 1 BOX, UNIT-DOSE	01/18/2021	
2		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	09/01/2017	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-0398) , repack(17856-0398)

Revised: 1/2021 ATLANTIC BIOLOGICALS CORP.