# DOCU 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.

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#### **Drug Facts**

## **Active ingredient**

Docusate Sodium 50 mg

### Purpose

Stool Softener Laxative

#### **Keep Out of Reach of Children**

#### Uses

- relieves occasional constipation
- generally produces bowel movement in 12-72

## Warnings

#### Do Not Use

- if you are presently taking mineral oil
- when abdominal pain, nausea, or vomiting are present
- for longer than one week

#### Ask a doctor before use if you have

noticed a sudden change in bowel habits that lasts over two weeks.

#### Ask a doctor or pharmacist before use if you are

taking any other drug. Take this product two or more hours before or after other drugs. Laxatives may affect how other drugs work.

#### Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use of this product

These may indicate a serious condition.

### 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**

- may be taken once daily or in divided doses
- give dose in 1/2 glass of milk, fruit juice or infant formula to mask bitter taste and prevent throat irritation

adults and children over 12	1 to 7 teaspoons
children 2 to under 12	1 to 3 teaspoons
children under 2	ask a doctor

#### Other information

- each teaspoon contains: sodium 5 mg
- shake well before using
- store at controlled room temperature 15° 30°C (59° 86°F)
- dispense contents with a child resistant closure in a tight, light resistant container as defined in the USP
- store in an upright position

## **Inactive Ingredients**

D&C Red #33, methylparaben, natural & artificial vanilla flavor, poloxamer 181, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium benzoate. Sodium citrate may be used to adjust pH.

Questions or comments? DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

20101 N.E 16TH PLACE MIAMI, FL 33179

Package/Label Principal Display Panel

# 17856-0771-01 STOOL SOFTENER (DOCUSATE SODIUM), LAXATIVE 250 MG/25 ML



See package insert for indications and dosage schedule

Store at controlled room temperature 15°-30°C (59°-86°F). Shake well before using Each teaspoon contains; sodium 5mg

\*\*\*Keep this andall medication out of the reach of children \*\*\*



17856-0771-01

Dosage: 25 ML

STOOL SOFTENER

Qty: 50 CUPS



GTIN: 00117856077114

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S/N: 00927201 Exp: 07/24/20

Lot: 009272

OTC

Packaged by Unit Dose Solutions Morrisville, NC 27560

Distributed by: AtlantioBiologicals Corp, Miami Fl 33179

Rev.09/19

Call to Reorder: 800.509.7592

## 17856-0771-02 STOOL SOFTENER (DOCUSATE SODIUM) LAXATIVE 100MG/10ML



See package insert for indications and dosage schedule

Store at controlled room temperature 15°-30°C (59°-86°F). Shake well before using.Each teaspoon contains; sodium 5mg
\*\*\*Keep this andall medication out of the reach of children\*\*\*



17856-0771-02

Dosage: 10 ML

STOOL SOFTENER

Qty: 72 CUPS



GTIN: 00117856077121

S/N: 00927301 Exp: 07/24/20 отс

Lot: 009273

Packaged by:Unit Dose Solutions Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp., Miami Fl 33179

Rev.09/19

Call to Reorder: 800.509.7592

# **DOCU LIQUID**

docusate sodium liquid

P	ro	d	uc	t	Info	r	ma	tio	n
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 Product Type
 HUMAN OTC DRUG
 Item Code (Source)
 NDC:17856-0771(NDC:50383-771)

 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			
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				

SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
WATER (UNII: 059QF0KO0R)		
POLOXAMER 181 (UNII: 09 Y8 E6 16 4A)		

Product Characteristics				
Color	PINK	Score		
Shape		Size		
Flavor	VANILLA (natural and artificial flavor)	Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:17856-0771- 1	50 in 1 BOX, UNIT-DOSE	0 1/3 1/2 0 2 0		
1		25 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product			
2	NDC:17856-0771- 2	72 in 1 BOX, UNIT-DOSE	0 1/3 1/2 0 2 0		
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	08/01/1997		

# Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment					
Name	Address	ID/FEI	Business Operations		
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-0771), repack(17856-0771)		

Revised: 1/2020 ATLANTIC BIOLOGICALS CORP.