# STOOL SOFTENER- docusate sodium capsule, liquid filled ATLANTIC BIOLOGICALS CORP.

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### **Drug Facts**

### Active ingredient (in each softgel)

Docusate sodium 250 mg

### **Purpose**

Stool softener laxative

#### Uses

- for relief of occasional constipation
- this product generally produces a bowel movement within 12 to 72 hours

### Warnings

#### Do not use

if you are presently taking mineral oil, unless directed by a doctor.

### Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that last over 2 weeks

### Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

### 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**

- adults and children 12 years of age and over: take 1 softgel daily or as directed by a doctor
- children under 12 years of age: ask a doctor

#### Other information

- each softgel contains: sodium 15 mg
- store between 20-25°C(68-77°F); excursions permitted between 15-30°C (59-86°F)

### **Inactive Ingredients**

edible white ink, FD&C red #40, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, propylene glycol, purified water, sorbitan sorbitol

### Questions or comments?

Call **1-800-616-2471** 

**Principal Display Panel** 

**Extra Strength** 

**Docusate Sodium** 

250 mg

Stool Softener

Laxative

Softgels

Distributed by:

ATLANTIC BIOLOGICALS CORP.

**MIAMI, FL 33179** 

**Product Label** 

MAJOR Extra Strength Docusate Sodium 250 mg

#### 17856-6999-01

DOCUSATE SODIUM
ES STOOL SOFTENER

LAXATIVE

of children\*\*

250mg PER SG DELIVERS 250mg/1SG

See package insert for indications and dosage schedule

Each softgel contains 15mg of Sodium. Store between 20-25°C (68-77°F); excursions permitted between 15-30°C (59-86°F). \*\*Keep this and all medications out of the reach



LIDOSE

17856-6999-01 Dosage 250mg/1SG

**DOCUSATE SODIUM ES** 

STOOL SOFTENER

GTIN: 00117856699910

.....

S/N:

Exp:

Lot:



Qty: 100 SOFTGELS

Distributed by: Atlantic Biologicals Corp. Miami, FL 33179

Rev.08/21

Call to Reorder: 800.509.7592

### **STOOL SOFTENER**

docusate sodium capsule, liquid filled

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:17856-6999(NDC:0904-6999)Route of AdministrationORAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 mg

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
MANNITOL (UNII: 30WL53L36A)			
SORBITAN (UNII: 6092ICV9RU)			

Product Characteristics			
Color	ORANGE	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	P20
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:17856- 6999-1	100 in 1 BOX, UNIT-DOSE	06/05/2024		
1	NDC:17856- 6999-2	1 in 1 POUCH; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	09/30/2019	

## Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
UNIT DOSE SOLUTIONS		360804194	repack(17856-6999)	

Revised: 6/2024 ATLANTIC BIOLOGICALS CORP.