

# **DOCUSATE SODIUM- docusate sodium liquid**

## **Bellevue Bio Science**

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### **Docusate Sodium Oral Liquid**

#### ***Active Ingredient (in each 10 mL)***

Docusate Sodium 100 mg

#### ***Purpose***

Stool Softener Laxative

#### ***Uses***

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

#### ***Warnings***

##### **Do not use**

- for more than 1 week unless directed by a doctor
- if you are currently 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 persist over a period of 2 weeks

##### **Stop use and ask a doctor if**

- you have rectal bleeding or failure to have a bowel movement after use of a laxative. 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 overdosage, get medical help or contact a Poison Control Center right away.

#### ***Directions***

- shake well before using

- must be given in a 6 oz to 8 oz glass of milk, fruit juice or infant formula to mask the bitter taste and prevent throat irritation
- take maximum dose daily until first bowel movement, dosage should then be reduced according to individual response
- do not exceed recommended dose
- follow dosing directions below or use as directed by a doctor

**1 teaspoonful = 5 mL**

<b>Age</b>	<b>Dose</b>
adults and children 12 years and older	1 to 7 teaspoonfuls
children 2 to under 12 years of age	1 to 3 teaspoonfuls
children under 2 years of age	ask a doctor

### ***Other Information***

- store at controlled room temperature 20°C to 25°C (68°F to 77°F)
- protect from light
- protect from excessive heat
- protect from freezing
- clear, grape-flavored liquid, supplied in the following:

NDC 81033-022-10: 10 mL unit dose cup

NDC 81033-022-50: Case containing 100 unit dose cups of 10 mL each

### ***Inactive ingredients***

citric acid, grape flavor, methylparaben, monoammonium glycyrrhizinate, potassium citrate, propylene glycol, propylparaben, purified water, sorbitol, sucralose

### ***Questions or comments?***

Call 1-833-537-4679

Packaged by:

**Kesin Pharma**

Oldsmar, FL 34677

Rev. 04/2025



***BULK SHIPMENT: For institutional or repackaging use only.***

Docusate Sodium Liquid

50 mg per 5 mL

200,00 mL

NDC: 8447-011-01

**Docusate Sodium Liquid**  
**50 mg per 5 mL**  
**200,000 mL**  
**NDC: 84447-011-01**

**Lot:**  
**Mfg:**

**BULK SHIPMENT**  
**PLEASE HANDLE CAREFULLY**

**Contains:**

50 mg Docusate Sodium Liquid per 5 mL; Inactive  
Ingredients: Purified Water, Propylene Glycol, Sorbitol,  
Grape Flavor, Sucralose, Potassium Citrate,  
Methylparaben, Propylparaben, Citric Acid,  
Monoammonium Glycyrhizinate

**\*\*Sugar, Alcohol, Gluten and Dye Free\*\***

**CAUTION:**  
**FOR REPACKAGING ONLY**  
Store at controlled room temperature 15°-30°C (59° - 86°F)

Density of 1.10 g/mL

**BELLEVIEW**  
**BIO SCIENCE**  
Manufactured by:  
Bellevue Biosciences LLC,  
Brooksville, FL 34604

Gross wt: _____
Tare wt: _____
Net wt: _____
Drum: _____ of _____

## DOCUSATE SODIUM

docusate sodium liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84447-011
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg in 10 mL

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	

<b>POTASSIUM CITRATE</b> (UNII: EE90ONI6FF)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>GRAPE</b> (UNII: 6X543N684K)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84447-011-01	200000 mL in 1 DRUM; Type 0: Not a Combination Product	03/01/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	03/01/2025	

**Labeler** - Belleview Bio Science (131968803)

### Establishment

Name	Address	ID/FEI	Business Operations
Belleview Bio Science		131968803	manufacture(84447-011) , analysis(84447-011) , label(84447-011)