

**DOCUSATE SODIUM LIQUID- docusate sodium liquid**  
**LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION**

*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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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 doctor 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

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Age  
 Adults and children over 12 years of age  
 Children under 12 years of age

Dose  
 1 to 6 teaspoons (50 mg - 300 mg)  
 Ask a doctor

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

Questions or comments? 1-866-595-5598

**Drugs Facts**

**Active Ingredients (per 5mL teaspoon) Purpose**  
 Docusate Sodium 50mg..... 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 doctor 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 a 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.

NDC 54859-813-16



**DOCUSATE SODIUM LIQUID**  
 50 mg/5mL

**CHERRY FLAVOR**  
 16 FL OZ (473 mL)

**Drug Facts (Continued)**

**Directions**• follow dosing directions below or use as directed by a physician • must be given in a 6oz to 8oz glass of milk or fruit juice to prevent throat irritation  
 • may be taken as a single daily dose or in divided 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 teaspoonful=5mL

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

**Other information**  
 •**Tamper-Evident**-do not use if foil over bottle opening is torn, broken, or missing • store at controlled room temperature 15-30°C (59-86°F) • protect from excessive heat • Pharmacist-Preserve and dispense in tight, light-resistant container with a child resistant cap as defined in the USP • each teaspoon(5ml) contains sodium 5mg  
**Inactive Ingredients:**FD&C red #40, flavor, methylparaben, poloxamer, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium benzoate, sodium citrate, and sucralose  
**Questions or comments? 1-866-595-5598**

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING  
 Code#: L-63 REV. 01/20



3 54859 81316 9

Lot. #  
 Exp. Date:

## DOCUSATE SODIUM LIQUID

docusate sodium liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:54859-813
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg in 5 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLOXAMER 124</b> (UNII: 1S66E28KXA)	

**POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A)

**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:54859-813-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/01/2021	

**Labeler** - LLORENS PHARMACEUTICALS INTERNATIONAL DIVISION (037342305)

Revised: 12/2021

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