

DOCUSATE SODIUM LIQUID- docusate sodium liquid
RUGBY LABORATORIES

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.

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 teaspoonful = 5 mL

Age	Dose
Adults and children over 12 years of age	1 to 6 teaspoons (50 mg - 300 mg)
Children under 12 years of age	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? 1-800-645-2158

Drugs Facts

Active Ingredients (per 5 mL teaspoon) Purpose
 Docusate Sodium 50 mg 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

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NDC 0536-1304-85

Docusate Sodium Liquid

50 mg/5 mL

Stool Softener

Cherry Flavored

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 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 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 = 5 mL


Age	Dose
Adults and children over 12 years of age	1 to 6 teaspoons (50 mg - 300 mg)
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 (5 mL) contains sodium 5 mg

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? 1-800-645-2158

THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING
 Code#: L-39

Rev. 07/20 R-164 Re-order No. 371040

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Distributed by:
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Lot, #
 Exp. Date:

DOCUSATE SODIUM LIQUID			
docusate sodium liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1304
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		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
POLOXAMER 124 (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:0536-1304-85	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	10/01/2020	

Labeler - RUGBY LABORATORIES (079246066)

Revised: 10/2020

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