

DOCUSATE SODIUM LIQUID- docusate sodium liquid

RUGBY LABORATORIES

Rugby- Ducosate 1304

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 doctore 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

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


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
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.

Distributed by:
RUGBY® LABORATORIES
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Livonia, MI 48152
www.rugbylaboratories.com

Lot, #
Exp. Date:



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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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 Drug		M007	10/01/2020	

Labeler - RUGBY LABORATORIES (079246066)