

## **DOCUSATE SODIUM LIQUID- docusate sodium liquid**

**Rij Pharmaceutical Corporation**

*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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### **Drug Facts**

#### **Active Ingredient (per teaspoonful = 5 mL)**

Docusate Sodium 50 mg

#### **Purpose**

Stool Softener

#### **Uses**

- prevents / relieves dry hard stool
- results usually occur 1 to 3 days after the first dose

#### **Warnings**

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

- when abdominal pain, nausea, or vomiting are present
- 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 lasts more than 2 weeks

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

- you have no bowel movement 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 health professional before use.

**Keep out of reach of children.** In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

#### **Directions**

- follow dosing directions below or take as directed by doctor
- must be given in a 6 to 8 oz glass of milk or fruit juice to prevent throat irritation
- may be taken as a single daily dose or in divided doses
- 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

Adults and children 12 years and over	1 to 4 teaspoons (50 to 200 mg)
Children under 12 years of age	ask a doctor

1 teaspoon = 5 mL

**TAMPER EVIDENT:** Do not use if breakaway band on cap is broken or missing.

**Other information**

- Store at room temperature 15°-30°C (59°-86°F)
- protect from excessive heat
- Keep tightly closed
- Dispense in tight, light resistant container as defined in the USP
- each teaspoon (5 mL) contains: sodium 15 mg

**Inactive ingredients**

citric acid, D&C Red #33, flavor, parabens, poloxamer, propylene glycol, sodium citrate, sorbitol, sucrose, and water.



NDC 53807-216-16

# DIOCTYL LIQUID

(Docusate Sodium)

50 mg/5 mL

\*COMPARE TO ACTIVE INGREDIENT IN COLACE® LIQUID

SHAKE WELL BEFORE USING  
KEEP TIGHTLY CLOSED

16 FL OZ (473 mL)

RIJ PHARMACEUTICAL CORPORATION  
40 COMMERCIAL AVENUE  
MIDDLETOWN, NY 10941

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\*This product is not manufactured or distributed by the owner of the registered trademark Colace® Liquid.

Rev. 06/12



## DOCUSATE SODIUM LIQUID

docusate sodium liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-216
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Docusate sodium (UNII: F05Q2T2JA0) (Docusate - UNII:M7P27195AG)	Docusate sodium	10 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
methylparaben (UNII: A2I8C7H9T)	
propylparaben (UNII: Z8IX2SC1OH)	
propylene glycol (UNII: 6DC9Q167V3)	
sodium citrate (UNII: 1Q73Q2JULR)	
water (UNII: 059QF0KO0R)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
SUCROSE (UNII: C15IH8M554)	
SORBITOL (UNII: 506T60A25R)	

## Product Characteristics

Color	PINK	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-216-08	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/16/1999	
2	NDC:53807-216-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/16/1999	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	03/16/1999	

**Labeler** - Rij Pharmaceutical Corporation (144679156)

## Establishment

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-216)