DOCUSATE SODIUM LIQUID- docusate sodium liquid
Geritrex LLC

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.

Docusate Sodium Liquid

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 assisstance 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 6 teaspoons (50 to 300 mg)
Children 2 to 12 years of age	1 to 3 teaspoons (50 to 150 mg)

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, methylparaben, parabens, poloxamer, polyethylene glycol 400, propylparaben, sodium citrate, sorbitol, sucrose, and water.

DOCUSATE SODIUM LIQUID

docusate sodium liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:54162-195
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**
anhydrous citric acid (UNII: XF417D3PSL)	
D&C red no. 33 (UNII: 9DBA0SBB0L)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
sodium citrate (UNII: 1Q73Q2JULR)	
water (UNII: 059QF0KO0R)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
SUCROSE (UNII: C151H8M554)	
SORBITOL (UNII: 506T60A25R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:54162-195-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/28/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/28/2017	

Labeler - Geritrex LLC (112796248)

Registrant - RIJ Pharmaceutical Corporation (144679156)

Revised: 9/2017 Geritrex LLC