

GERICARE DOCUSATE SODIUM LIQUID- docusate sodium liquid
GERI-CARE PHARMACEUTICALS, CORP

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 (irregularity)
- generally produces bowel movement in 12 to 72 hours

Warnings

Do not use for more than one week unless directed by a doctor.

Ask a doctore before use if you

- have stomach pain, nausea or vomiting
- hadve sudden change in bowel habits that persits over a period of 2 weeks
- are taking mineral oil

Stop use and ask doctor if

- you have rectal bleeding or fail to have a bowel movement afrer use of this product. 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

shake well before using

- follow dosing directions below or use as directed by a physician
- do not exceed recommended dose
- 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

1 teasponnful = 5 mL

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

1 to 6 teaspoons (5 mL - 30 mL)
 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? 1-800-540-3765

<p>Drug Facts</p> <p>Active ingredients (per 5mL/teaspoon) Purpose Docusate Sodium 50mg.....Stool Softener Laxative</p> <p>Uses</p> <ul style="list-style-type: none"> relieves occasional constipation (irregularity) generally produces bowel movement in 12 to 72 hours <p>Warnings Do not use for more than one week unless directed by a doctor.</p> <p>Ask a doctor before use if you</p> <ul style="list-style-type: none"> have stomach pain, nausea or vomiting have a sudden change in bowel habits that persists over a period of 2 weeks are presently taking mineral oil <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> you have rectal bleeding or fail to have a bowel movement after use of this product. These could be signs of a serious condition. a skin rash occurs you experience throat irritation <p>If pregnant or breast-feeding, ask a doctor before use.</p> <p>Keep out of reach of children. In case of accidental overdose, seek medical assistance or contact a Poison Control Center right away.</p> <p>Code#: L-97 Rev. 09/20</p> <p>Lot.# Exp. Date:</p>	<p>NDC 57896-413-16</p>  <p>DOCUSATE SODIUM LIQUID</p> <p>STOOL SOFTENER LAXATIVE 50 mg/5mL</p> <p>CHERRY FLAVOR</p> <p>16 FL OZ (473 mL)</p>	<p>Drug Facts (continued)</p> <p>Directions • shake well before using</p> <ul style="list-style-type: none"> follow dosing directions below or use as directed by a physician do not exceed recommended dose must be given in a 6oz to 8oz glass of milk or fruit juice to prevent throat irritation may be taken as a single dose or in divided doses take maximum dose daily until first bowel movement, dosage should then be reduced according to individual response <p style="text-align: center;">1 teaspoonful=5mL</p> <table border="1"> <thead> <tr> <th>Age</th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>Adults and children 12 years of age and over</td> <td>1 to 6 teaspoonfuls (5 mL-30 mL)</td> </tr> <tr> <td>Children under 12 years of age</td> <td>Ask a doctor</td> </tr> </tbody> </table> <p>Other information</p> <ul style="list-style-type: none"> each teaspoonful (5ml) contains: sodium 5 mg store at room temperature 15°- 30° (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 Tamper-Evident: Do not use if foil over bottle opening is torn, broken, or missing. <p>Inactive ingredients: FD&C red #40, flavor, methylparaben, poloxamer, polyethylene glycol, propylene glycol, propylparaben, purified water, sodium benzoate, sodium citrate, and sucralose</p> <p>Questions or comments? 1-800-540-3765</p> <p style="text-align: center;">THIS IS A BULK CONTAINER NOT INTENDED FOR DISPENSING</p>  <p style="text-align: right;">DIST. BY: GERI-CARE PHARMACEUTICALS CORP. 1650 63rd Street Brooklyn, NY 11204</p>	Age	Dose	Adults and children 12 years of age and over	1 to 6 teaspoonfuls (5 mL-30 mL)	Children under 12 years of age	Ask a doctor
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GERICARE DOCUSATE SODIUM LIQUID

docusate sodium liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-413
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: 3WJQ05DW1A)	
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:57896-413-16	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 - GERI-CARE PHARMACEUTICALS, CORP (611196254)

Revised: 7/2021

GERI-CARE PHARMACEUTICALS, CORP