

**STOOL SOFTENER- docusate sodium capsule, liquid filled**  
**Geri-Care Pharmaceutical Corp**

-----  
**gc 401**

**Active ingredient (in each softgel)**

Docusate Sodium 100 mg

**Purpose**

Stool Softener

**Uses**

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

**Warnings**

**Ask a doctor before use if you**

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

**Stop use and ask a doctor if**

- you have rectal bleeding or fail to have a bowel movement.

These could be signs of a serious condition.

- you need to use a laxative for longer than 1 week

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- do not exceed recommended dose
- adults and children 12 years and older: take 1-3 softgels daily, usually 1 softgel daily after the first bowel movement, or as directed by a doctor.
- children under 12: ask a doctor

**Other information**

- **each softgel contains:** sodium 5 mg. Very low sodium
- store at 59°-77°F (15°-25°C)
- keep tightly closed
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.

## Inactive ingredients

citric acid, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, PEG, propylene glycol, purified water, sorbitol sorbitan solution, white edible ink.

## Questions or comments?

1-800-540-3765

## Package Label

NDC 57896-411-01  
GERI-CARE®

**STOOL SOFTENER**  
DOCUSATE SODIUM 100 mg

Compare to the active ingredient in COLACE® Regular Strength\*

100 Softgels

**Drug Facts**

**Active ingredient (in each softgel)**  
Docusate Sodium 100 mg.....Stool Softener

**Uses**

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

**Warnings**

Ask a doctor before use if you

- have stomach pain, nausea or vomiting
- noticed a sudden change in bowel habits that lasts for over 2 weeks
- are presently taking mineral oil

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement
- These could be signs of a serious condition.
- you need to use a laxative for longer than 1 week

if pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- do not exceed recommended dose
- adults and children 12 years and older: take 1-3 softgels daily, usually 1 softgel daily after the first bowel movement, or as directed by a doctor.
- children under 12: ask a doctor

**Other information**

- each softgel contains: sodium 5 mg. Very low sodium
- store at 59°-77°F (15°-25°C)
- keep tightly closed
- protect from excessive humidity
- Tamper Evident: Do not use if imprinted seal under cap is missing or broken.

**Inactive ingredients:** citric acid, FD&C Red #40, FD&C Yellow #6, gelatin, glycerin, PEG, propylene glycol, purified water, sorbitol sorbitan solution, white edible ink.

**Questions or comments? 1-800-540-3765**

\*This product is not manufactured or distributed by the owner of the registered trademark COLACE®.  
REV 1223P  
Product of China  
DIST. BY: GERI-CARE PHARMACEUTICALS CORP.  
1295 Towbin Ave, Lakewood, NJ 08701

3 57896 41101 5

## STOOL SOFTENER

docusate sodium capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-411
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

### Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (OVAL)	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	PC1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-411-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	
2	NDC:57896-411-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	01/01/2024	

**Labeler** - Geri-Care Pharmaceutical Corp (611196254)

**Registrant** - Geri-Care Pharmaceutical Corp (611196254)