

**STOOL SOFTENER WITH LAXATIVE- docusate sodium and sennosides tablet, film coated**

**Geri-Care Pharmaceutical Corp**

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**Gericare 303B (304)**

**Active ingredient (in each tablet)**

Docusate Sodium 50 mg

Sennosides 8.6 mg

**Purpose**

Stool softener

Stimulant laxative

**Uses**

- relieves occasional constipation (irregularity)
- this product generally produces bowel movement in 6 to 12 hours

**Warnings**

**Do not use**

- laxative products for longer than 1 week unless directed by a doctor
- if you are presently taking mineral oil, unless directed by a doctor

**Ask a doctor before use if you have**

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

**Stop use and ask a doctor if** you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could

be signs of a serious condition.

**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**

- Take only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses

adults and children 12 years and over	take 2-4 tablets daily
children under 12 years of age	ask a doctor

### Other information

- each tablet contains: **calcium 20 mg, sodium 3 mg**
- store at controlled room temperature
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.
- product of India

### Inactive ingredients

cellulose, croscarmellose sodium, dicalcium phosphate, FD&C blue #2 lake, FD&C red #40 lake, hypromellose, magnesium stearate, PEG, silica, talc, titanium dioxide.

### Package Label

<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each tablet)</b></p> <p>Docusate Sodium 50 mg.....Stool softener Sennosides 8.6 mg.....Stimulant Laxative</p> <p><b>Purpose</b></p> <p>Stool softener Stimulant Laxative</p> <p><b>Uses</b> • relieves occasional constipation (irregularity) • this product generally produces a bowel movement in 6 to 12 hours</p> <p><b>Warnings</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>• laxative products for longer than 1 week unless directed by a doctor</li> <li>• if you are presently taking mineral oil, unless directed by a doctor</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>• stomach pain • nausea • vomiting</li> <li>• noticed a sudden change in bowel habits that lasts over 2 weeks</li> </ul> <p><b>Stop use and ask a doctor if you have</b> rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away. ▶</p>	<p>NDC 57896-304-01</p> <p><b>HEALTH STAR</b>®</p> <p><b>STOOL SOFTENER with laxative</b></p> <p><b>DOCUSATE SODIUM 50 mg SENNOSIDES 8.6 mg</b></p> <p>Compare to active ingredients in <b>PERI-COLACE</b>®*</p> <p><b>100 Tablets</b></p>	<p><b>Directions</b> • Take only by mouth. Doses may be taken as a single daily dose, preferably in the evening, or in divided doses.</p> <table border="1"> <tr> <td>adults and children 12 years and over</td> <td>take 2-4 tablets daily</td> </tr> <tr> <td>children under 12 years</td> <td>ask a doctor</td> </tr> </table> <p><b>Other information</b> • each tablet contains: <b>calcium 20 mg, sodium 3 mg</b> • store at controlled room temperature</p> <ul style="list-style-type: none"> <li>• <b>Tamper Evident:</b> Do not use if imprinted seal under cap is missing or broken. • product of India</li> </ul> <p><b>Inactive ingredients:</b> cellulose, croscarmellose sodium, dicalcium phosphate, FD&amp;C blue #2 lake, FD&amp;C red #40 lake, hypromellose, magnesium stearate, PEG, silica, talc, titanium dioxide.</p> <p>* This product is not manufactured or distributed by the owner of the registered trademark Peri-Colace®. REV 0323B</p> <p>Dist. By: Geri-Care Pharmaceuticals Corp. 1295 Towbin Avenue Lakewood, NJ 08701</p> <p>3 57896 30301 3</p>	adults and children 12 years and over	take 2-4 tablets daily	children under 12 years	ask a doctor
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## STOOL SOFTENER WITH LAXATIVE

docusate sodium and sennosides tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57896-304
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SENNOSIDES</b> (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	PSD21
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-304-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2019	
2	NDC:57896-304-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	12/01/2019	

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

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