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

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**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

• have a sudden change in bowel habits that persists over a period of 2 weeks

• are presently taking mineral oil

**Stop use and ask a doctor if**

• you need to use a laxative longer than 1 week

• you have rectal bleeding or fail to have a bowel movement. 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**

- 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 7 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

FD&C red #40, FD&C yellow #6 (sunset yellow), gelatin, glycerol, PEG, sorbitol special, water.

### Questions or comments?

**1-800-540-3765**

### Package Label


## STOOL SOFTENER

docusate sodium capsule, liquid filled

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:57896-401 |
| **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** |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |

| | |
|---|---|
| **GELATIN** (UNII: 2G86QN327L) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **MANNITOL** (UNII: 3OWL53L36A) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | red (reddish) | **Score** | no score |
| **Shape** | OVAL | **Size** | 12mm |
| **Flavor** | | **Imprint Code** | SCU1 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:57896-401-10 | 1000 in 1 BOTTLE; Type 0: Not a Combination Product | 09/01/2020 | |
| **2** | NDC:57896-401-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 09/01/2020 | |
| **3** | NDC:57896-401-03 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 09/01/2020 | |
| **4** | NDC:57896-401-20 | 200 in 1 BOTTLE; Type 0: Not a Combination Product | 09/01/2020 | |
| **5** | NDC:57896-401-25 | 250 in 1 BOTTLE; Type 0: Not a Combination Product | 09/20/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M007 | 01/01/2000 | |

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

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

Revised: 10/2023 Geri-Care Pharmaceutical Corp