

STOOL SOFTENER- docusate sodium tablet
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.

Gericare 421

Active ingredient

Docusate Sodium 100 mg

Purpose

Stool Softener Laxative

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

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

Directions

- adults and children 12 years and older: take 1-3 tablets daily until first bowel movement; 1 tablet daily thereafter, or as directed by doctor
- children under 12: consult a doctor
- do not exceed recommended dose

Other information

- each tablet contains: **calcium 50 mg, sodium 8 mg**
- store at room temperature 15°C-30°C (59°F-86°F)
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken

Inactive ingredients

cellulose, croscarmellose sodium, dicalcium phosphate, magnesium stearate, silica, stearic acid, talc

Questions or comments?

1-800-540-3765

PACKAGE LABEL

<p>Drug Facts</p> <p>Active ingredient (in each tablet) Purpose Docusate Sodium 100 mg.....Stool Softener Laxative</p> <p>Uses • relieves occasional constipation (irregularity) • generally produces bowel movement in 12 to 72 hours</p> <p>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</p> <p>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.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p>	<p>NDC 57896-421-01</p> <p>GERI-CARE®</p> <p>STOOL SOFTENER</p> <p>DOCUSATE SODIUM 100 mg</p> <p> Tablets</p> <p>100 Tablets 100 mg each</p>	<p>Directions • do not exceed recommended dose • adults and children 12 years and older: take 1-3 tablets daily until first bowel movement; 1 tablet daily thereafter, or as directed by a doctor • children under 12: consult a doctor</p> <p>Other information • each tablet contains: calcium 50 mg, sodium 8 mg • store at room temperature 15°C-30°C (59°F-86°F) Tamper Evident: Do not use if imprinted seal under cap is missing or broken.</p> <p>Inactive ingredients cellulose, croscarmellose sodium, dicalcium phosphate, magnesium stearate, silica, stearic acid, talc</p> <p>Questions or comments? 1-800-540-3765</p> <p>DIST. BY: GERI-CARE PHARMACEUTICALS CORP. 1650 63rd Street Brooklyn, NY 11204</p> <p>REV 0519</p> 
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STOOL SOFTENER

docusate sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-421(NDC:75841-421)
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
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	GC422
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-421-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2015	
2	NDC:57896-421-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2015	
3	NDC:57896-421-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	09/01/2015	

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - GCP Laboratories (965480861)

Establishment

Name	Address	ID/FEI	Business Operations
GCP Laboratories		965480861	manufacture(57896-421) , relabel(57896-421)

Revised: 12/2019

Geri-Care Pharmaceuticals, Corp