

STOOL SOFTENER- docusate sodium tablet
Geri-Care Pharmaceuticals, Corp

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, or as directed by a doctor. May be taken as a single daily dose or in divided doses.
- children under 12: consult a doctor

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, sodium benzoate, silica, stearic acid, talc

Questions or comments?

1-800-540-3765

PACKAGE LABEL

Drug Facts

Active ingredient (in each tablet) **Purpose**
Docusate Sodium 100 mg.....Stool Softener Laxative

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NDC 57896-421-01

GERI CARE®

STOOL SOFTENER
DOCUSATE SODIUM 100 mg

 **Tablets**

100 TABLETS 100 MG EACH

Drug Facts (continued)

Directions • do not exceed recommended dose
• adults and children 12 years and older: take 1-3 tablets daily, or as directed by a doctor. May be taken as a single daily dose or in divided doses.
• children under 12: consult a doctor

Other information
• **each tablet contains:** calcium 50 mg, sodium 10 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, sodium benzoate, stearic acid, talc

Questions or comments? 1-800-540-3765

DIST. BY: **GERI-CARE PHARMACEUTICALS CORP.**
1295 Towbin Ave, Lakewood, NJ 08701

REV 0922

3

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4

STOOL SOFTENER

docusate sodium tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-421
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
SODIUM BENZOATE (UNII: OJ245FE5EU)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
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 Drug	M007	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)

Revised: 10/2023

Geri-Care Pharmaceuticals, Corp