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.

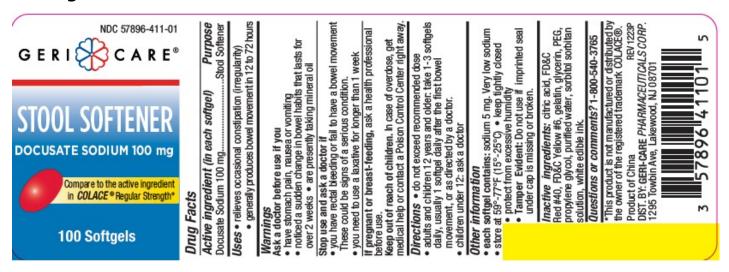
Inactive ingredients

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



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

-	_
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITAN (UNII: 6092ICV9RU)	

Product Characteristics			
Color	red	Score	no score
Shape	CAPSULE (OVAL)	Size	13mm
Flavor		Imprint Code	PC1
Contains			

P	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)

Revised: 2/2024 Geri-Care Pharmaceutical Corp