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

Active ingredient (in each softgel)

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. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

• adults and children 12 years and older: take 1-2 softgel daily until first bowel movement; 1 softgel daily thereafter, or as directed by doctor

- children under 12: consult a doctor
- do not exceed recommended dose

Other information

- each softgel contains: sodium 5 mg. very low sodium
- store at 15°C-25°C(59° F-77° F)
- keep tightly closed

- product from USA or Canada
- **Tamper Evident:** Do not use if imprinted seal under cap is missing or broken.

Inactive ingredients

FD and C red 40, gelatin, glycerin, edible ink, PEG, propylene glycol, sorbitol special, water. May also contain D and C yellow 10, FD and C yellow 6 (sunset yellow), mannitol.

Package Label

GERICARE

NDC 57896-401-01

Stool Softener

compare to active ingredient in colace

Docusate Sodium

100 Softgels

100 mg each

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	100 Softgels 100 mg each	Drug I Active I Doousati	Warning Ask a do or vomiti stop use Stop use medical I medical I Directic e do not

STOOL SOFTENER						
docusate sodium capsule, liquid fill	ed					
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Sourc	e)	NDC:5789	NDC:57896-401	
Route of Administration	ORAL					
Active Ingredient/Active Moi	ety					
Ingredient Name			Basis of S	strength	Strength	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)			DOCUSATE SODIUM		100 mg	
Inactive Ingredients						
	Ingredient Name			St	rength	

FD&C RED NO.40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO.6 (UNII: H77VEI93A8)	
MANNITOL (UNII: 30WL53L36A)	

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:57896-401-01	100 in 1 BOTTLE			
2 NDC:57896-401-10	1000 in 1 BOTTLE			
3 NDC:57896-401-03	30 in 1 BOTTLE			
4 NDC:57896-401-25	250 in 1 BOTTLE			
Marketing Information				

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	0 1/0 1/20 0 0	

Labeler - Geri-Care Pharmaceutical Corp (611196254)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 4/2013

Geri-Care Pharmaceutical Corp