STOOL SOFTENER- docusate sodium capsule, liquid filled RMT HEALTH LLC

crw 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 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, until first bowel movement; 1 softgel daily thereafter, 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, purified water.

Questions or comments?

1-800-540-3765

Package Label



STOOL SOFTENER

docusate sodium capsule, lic	juid filled				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (So	urce)	NDC:851	11-401
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingr	edient Name		Basis of St	rength	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)		

Product Character	Product Characteristics			
Color	red (reddish)	Score	no score	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code	SCU1	
Contains				

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:85111-401- 10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2025		
2	NDC:85111-401- 50	500 in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2025		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	09/01/2025	

Labeler - RMT HEALTH LLC (132906621)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 12/2025 RMT HEALTH LLC