DOCUSATE SODIUM- docusate sodium capsule, liquid filled Spirit Pharmaceuticals LLC

Docusate Sodium 100mg

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 100 mg

Purpose

Stool Softner

Uses

- for temporary relief of occasional constipation and irregularity
- this product generally produces a bowel movement within 12 to 72 hours

Warnings

Ask a doctor before use if you have

- stomach pain, nausea or vomittiong
- a sudden change in bowel habits that lasts more than 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use laxative for more 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.1(800)222-1222

Directions

• take only by mouth. Doses may be taken as a single daily dose or in divided doses.

Adults and children 12	1 to 3 softgels daily. This dose may be taken as a single daily
years and over	dose or in divided doses
Children 2 to under 12	1 softgel daily.
years of age	
Children under 2 years of	Ask a doctor
age	

Other information

- Store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F)
- Keep tightly closed

Inactive ingredients

FD&C Red#40, FD&C Yellow#6, gelatin, glycerin, polyethylene glycol 400, propylene glycol, purified water, sorbitol solution, titanium dioxide.

Questions or comments?

1-888-333-9792

PDP

Cabinet: Stool Softener Docusate Sodium 100mg

75 Softgels



DOCUSATE SODIUM

docusate sodium capsule, liquid filled

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68210-4104 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		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
SORBITOL (UNII: 506T60A25R)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics			
Color	red	Score	no score
Shape	CAPSULE	Size	12mm
Flavor		Imprint Code	125
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:68210- 4104-1	75 in 1 PACKAGE; Type 0: Not a Combination Product	07/02/2020		
2	NDC:68210- 4104-0	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	07/02/2020	

Revised: 12/2023 Spirit Pharmaceuticals LLC