STOOL SOFTENER AND LAXATIVE- docusate sodium and sennosides tablet, film coated Spirit Pharmaceuticals LLC

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.

Stool Softener and Laxative

Drug Facts

Active Ingredient (in each tablet)

Docusate sodium 50 mg

Sennosides 8.6 mg

Purpose

Stool softener

Laxative

Uses

• relieves occasional constipation (irregularity) • generally produces bowel movement in 6–12 hours

Warnings

• relieves occasional constipation (irregularity) • generally produces bowel movement in 6–12 hours

Do not use

• if you are now taking mineral oil, unless directed by a doctor • laxative products for longer than 1 week, unless directed by a doctor

Ask a doctor before use if you have

• stomach pain • nausea • vomiting • noticed a sudden change in bowel habits that continues over a period of 2 weeks

Ask a doctor or pharmacist before use

if you are if you have rectal bleeding or fail to have a bowel movement after use of a laxative. These may indicate a serious condition.

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 a stool softener 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 preferably at bedtime or as directed by a doctor

Age	Starting Dosage	Maximum Dosage
adults & children 12 years of age & over	2 tablets once a day	4 tablets twice a day
children 6 to under 12 years of age	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years	½ tablet once a day	1 tablet twice a day
children under 2 years	ask a doctor	ask a doctor

Other information

- each tablet contains: calcium 20 mg and sodium 6 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

Colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate, D&C Yellow No. 10, FD&C Yellow No. 6, hypromellose, magnesium stearate, microcrystalline cellulose, maltodextrin, polyethylene glycol 400, purified water, sodium benzoate, stearic acid, titanium dioxide

Questions or comments?

1-888-333-9792

Distributed by:

Cabinet Health P.B.C.

Pouch



CABINET:

Stool Softener & Laxative

Compare to the active ingredients in: Senokot-S®*

Active ingredients: DOCUSATE SODIUM 50 MG SENNOSIDES 8.6 MG

Relieves Occasional Constipation Gentle, Dependable Overnight Relief

COMPOSTABLE REFILL POUCH

Includes:

50 x Tablets

1 x Magnetic Label

1 x Drug Facts Booklet



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CABINET: The Sustainable Healthcare Co.™

docusate sodium and sennosides tablet, film coated

Product Information

Product Type HUMAN OTC I	RUG Item Code (Source) NDC:68210-4180
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Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX)	SENNOSIDES	8.6 mg

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
CALCIUM PHOSPHATE (UNII: 97Z1W3NDX)			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			

Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	10mm	
Flavor		Imprint Code	S44	
Contains				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:68210- 4180-5	50 in 1 POUCH; Type 0: Not a Combination Product	11/22/2021	

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	Marketing End	
Category	Citation	Date	Date	

OTC monograph not final	part334	11/22/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2022 Spirit Pharmaceuticals LLC