

STOOL SOFTENER WITH STIMULANT LAXATIVE- docusate sodium, sennosides tablet
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

Drug Facts

Active ingredients (in each tablet)

Docusate sodium 50 mg
Sennosides 8.6 mg

Purpose

Stool softener
Stimulant Laxative

Uses

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

Warnings

Do not use

- laxative products for longer than 1 week unless directed by a doctor
- if you are presently taking mineral oil, 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 lasts over 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.

Drug Facts (continued)

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, preferably in the evening, or in divided doses

adults and children 12 years and over	take 2-4 tablets daily
children 6 to under 12 years of age	take 1-2 tablets daily
children 2 to under 6 years of age	take up to 1 tablet daily
children under 2	ask a doctor

Other information

- **each tablet contains:** calcium 20 mg, 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, FD&C Red #40, hypermellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol-400, purified water, sodium benzoate, stearic acid, titanium dioxide

Questions or comments?

☎1-888-333-9792

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Carton

COMPARE TO THE ACTIVE
INGREDIENTS OF PERI-COLACE®†

FAMILY WELNESS

Stool Softener

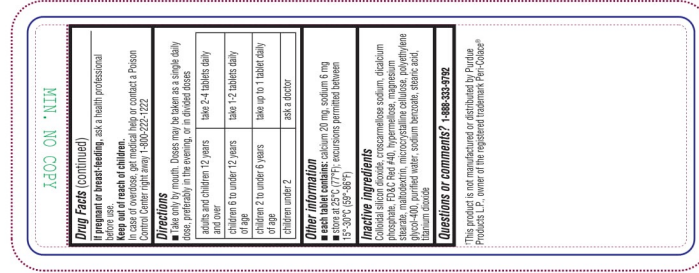
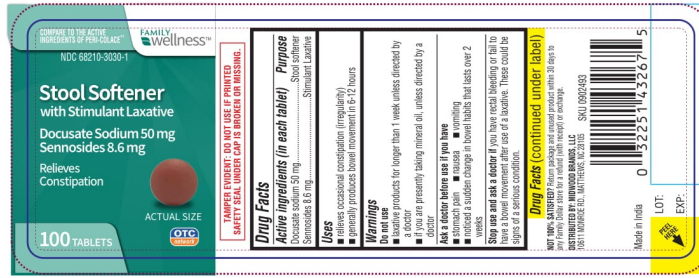
with Stimulant Laxative

Docusate Sodium 50 mg
Sennosides 8.6 mg

Relieves
Constipation

ACTUAL SIZE

100 TABLETS



STOOL SOFTENER WITH STIMULANT LAXATIVE

docusate sodium, sennosides tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-3030
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: 3FYP5M0IUX) (SENNOSIDES - UNII:3FYP5M0IUX)	SENNOSIDES	8.6 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	S44
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-3030-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/01/2018	

Labeler - SPIRIT PHARMACEUTICALS LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
ELYSIUM PHARMACEUTICALS LIMITED		915664486	manufacture(68210-3030)

Revised: 10/2018

SPIRIT PHARMACEUTICALS LLC