SENNA-S- docusate sodium and 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.

VALUMEDS SENNA-S

Drug Facts

Active ingredients (in each tablet)

Docusate sodium 50 mg
Sennosides 8.6 mg

Purpose

Stool Softner

Laxative

Uses

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

Warnings

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 lasts over a period of 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 may indicate 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 1(800)222-1222

Directions

- take preferably at bedtime or as directed by a doctor

Age	Starting Dosage	Maximum Dosage
adults and children 12 years of age or over	2 tablets once a day	4 tablets twice a day
children 6 to under 12 years	1 tablet once a day	2 tablets twice a day
children 2 to under 6 years	1/2 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 19.92 mg, sodium 5.61 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

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

PRINCIPAL DISPLAY PANEL - 100 count bottle

VALUMEDS

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

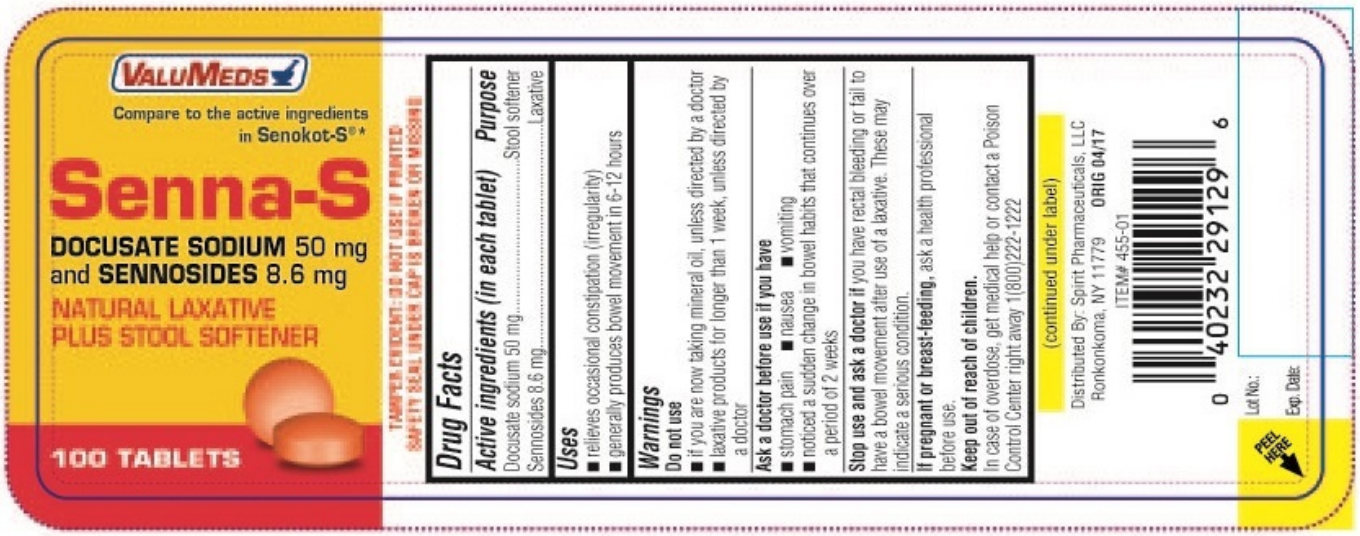
SENNA-S

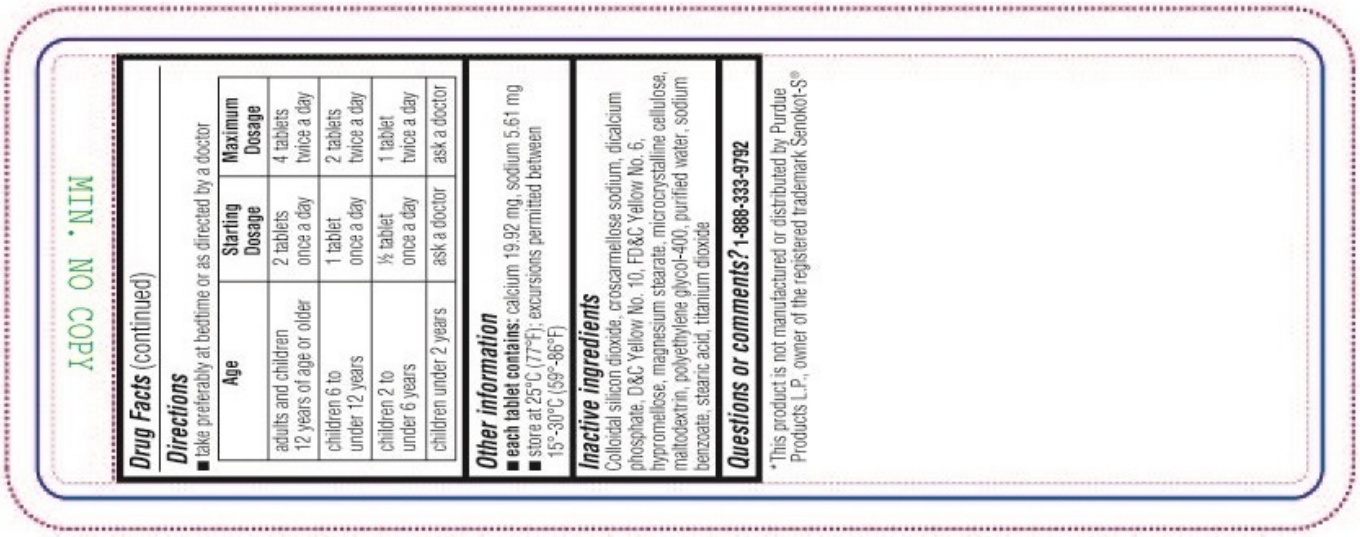
DOCUSATE SODIUM 50 mg

and **SENNOSIDES 8.6 mg**
NATURAL LAXATIVE

PLUS STOOL SOFTENER

100 TABLETS





SENNA-S

docusate sodium and sennosides tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-0302
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)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE, UNSPECIFIED (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	orange	**Score**	no score
Shape	ROUND (biconvex)	**Size**	10mm
Flavor		**Imprint Code**	S35
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68210-0302-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2017	
2	NDC:68210-0302-3	1 in 1 CARTON	04/11/2018	
2		30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	05/19/2017	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals LTD		915664486	manufacture(68210-0302)

Revised: 4/2018 Spirit Pharmaceuticals LLC