# SENNA-S- senna and docusate sodium tablets, 8.6 mg tablet, coated We Care Distributor Inc.

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.

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### Senna-S - Senna and Docusate Sodium Tablets, 8.6 mg

#### **Drug Facts**

Active Ingredient (in each tablet)	Purpose
Docusate Sodium 50 mg	Stool Softener
Sennosides 8.6 mg	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 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.

#### **Directions**

#### take preferably at bedtime or as directed by a doctor

- adults and children 12 years of age or older starting dosage: 2 tablets once a day, maximum dosage: 4 tablets twice a day
- children 6 to under 12 years starting dosage: 1 tablet once a day, maximum dosage: 2 tablets twice a

day

- children 2 to under 6 years starting dosage: 1/2 tablet once a day, maximum dosage: 1 tablet twice a day
- children under 2 years starting dosage: ask a doctor, maximum dosage: ask a doctor

#### Other information

- each tablet contains: calcium 21 mg
- each tablet contains: sodium 3 mg VERY LOW SODIUM
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

#### **Inactive ingredients**

croscarmellose sodium, colloidal silicon dioxide, dicalcium phosphate, D&C Yellow # 10, FD&C Yellow # 6, hypromellose, microcrystalline cellulose, magnesium stearate, maltodextrin, polyethylene glycol, stearic acid, titanium dioxide

#### Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

#### PRINCIPAL DISPLAY PANEL

Compare to the Active Ingredients inSenokot-S®

Senna and Docusate Sodium Tablets, 8.6 mg and 50 mg

# TO OPEN PUSH IN TAB AND PULL OUT

25 Pouches of 2 Tablets Each







### **SENNA-S**

senna and docusate sodium tablets, 8.6 mg tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-016
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SENNO SIDES (UNII: 3FYP5M0 IJX) (SENNO SIDES - UNII:3FYP5M0 IJX)	SENNOSIDES	8.6 mg	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg	

Inactive Ingredients				
Ingredient Name	Strength			
CROSCARMELLOSE SODIUM (UNII: M28 O L1HH48)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTO DEXTRIN (UNII: 7CVR7L4A2D)				
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				

Product Characteristics				
Color	orange	Score	no score	
Shape	ROUND	Size	10 mm	
Flavor		Imprint Code	S35	
Contains				

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70005-016-25	25 in 1 BOX		
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-016-50	50 in 1 BOX		
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-016-02	2 in 1 POUCH		
3		2 in 1 POUCH; 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	03/07/2016	

## **Labeler** - We Care Distributor Inc. (079832998)

Establishment				
Name	Address	ID/FEI	Business Operations	
Elysium Pharmaceutical Ltd.		915664486	manufacture(70005-016)	

Revised: 3/2016 We Care Distributor Inc.