# SENNA-S- senna and docusate sodium tablets, 8.6 mg and 50 mg tablet Advance Pharmaceutical 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 & 50 mg

**Drug Facts** 

#### ACTIVE INGREDIENT

Senna Tablets- 8.6 mg

Docusate Sodium- 50 mg

#### **PURPOSE**

Senna Tablets- 8.6 mg ......Laxative

Docusate Sodium- 50 mg......Stool softner

#### 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)
- read all product information before using
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

## **Inactive ingredients**

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

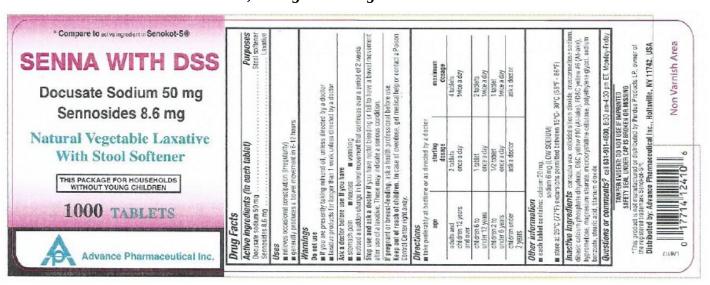
### Questions or comments?

call 631-981-4600, 8.30 am-4.30 pm ET, Monday - Friday TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

#### PRINCIPAL DISPLAY PANEL

NDC-17714-124-10

Senna and Docusate Sodium Tablets, 8.6 mg and 50 mg



# SENNA-S senna and docusate sodium tablets, 8.6 mg and 50 mg tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:17714-124

Route of Administration

ORAL

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

Inactive Ingredients	
Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0 EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
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)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
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	TCL;081
Contains			

Packaging				
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NDC:17714-124-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	0 2/0 1/20 17	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	0 2/0 1/20 17	

# Labeler - Advance Pharmaceutical Inc. (078301063)

# **Registrant** - Advance Pharmaceutical Inc. (078301063)

Establishment				
Name	Address	ID/FEI	Business Operations	
Time Cap Laboratories, Inc.		037052099	manufacture(17714-124)	

Revised: 10/2017 Advance Pharmaceutical Inc.