

**SENNAS- 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.

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 mgLaxative

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

carnauba 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 WITH DSS
Docusate Sodium 50 mg
Sennosides 8.6 mg
Natural Vegetable Laxative With Stool Softener
 THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN
1000 TABLETS
 Advance Pharmaceutical Inc.

Drug Facts
Active ingredients (in each tablet)
 Docusate sodium 50 mg Stool softener
 Sennosides 8.6 mg Laxative

Purposes
 Relieves occasional constipation (irregularity).
 Generally produces a bowel movement in 6-12 hours.

Warnings
Do not use
 ■ If you are presently taking antacids, unless directed by a doctor.
 ■ If you have been taking laxatives for longer than 1 week, unless directed by a doctor.

Ask a doctor before use if you have
 ■ stomach pain ■ nausea ■ vomiting
 ■ a sudden change in bowel movement that continues 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.

Directions
 ■ Take 1 or 2 tablets, as directed by a doctor.
 ■ Take preferably at bedtime or as directed by a doctor.

age	starting dosage	maximum dosage
adults and children 12 years and 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 21 mg, sodium 3 mg (LOW SODIUM)
 ■ store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)

Inactive ingredients carnauba wax, colloidal silicon dioxide, croscarmellose sodium, docusate sodium, FD&C yellow #10 (All-Label), FD&C yellow #6 (All-Label), hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, sodium benzoate, 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
 Distributed by: Advance Pharmaceutical Inc., Holtsville, NY 11742, USA

0 17714 12410 6
 Non Varnish Area

SENNAS

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
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Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	TCL;081
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17714-124-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	02/01/2017	

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.