SENNA- sennosides 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 8.6mg tabs

Active ingredient (in each tablet)

Sennosides 8.6 mg

Purpose

Laxative

Uses

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

Warnings

Do not use

• 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 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.

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

a ge	starting dosage	maximum dosage
adults and children 12 years of age	2 tablets once a day	4 tablets twice a day
or older		
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 25 mg, sodium 2mg (very low sodium)
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

croscarmellose sodium, dibasic calcium phosphate dihydrate, hypromellose, , magnesium stearate, microcrystalline cellulose, mineral oil

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: 17714-122-01

Senna 8.6mg



SENNA

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:17714-122

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

SENNOSIDES A AND B (UNII: 1B5FPI42EN) (SENNOSIDES A AND B - UNII:1B5FPI42EN) SENNOSIDES A AND B 8.6 mg

Inactive Ingredients

mactive ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 OL 1HH48)		
CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)		
HYPROMELLOSES (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
MINERAL OIL (UNII: T5L8T28FGP)		

Product Characteristics

1 Todact Characteristics				
Color	bro wn	Score	no score	
Shape	ROUND	Size	9 m m	
Flavor		Imprint Code	TCL080	
Contains				

Packaging

ı					
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1	NDC:17714-122-01	100 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)

Esta	h	lia	hm	ont
нста	m	ше	nm	ent

Name	Address	ID/FEI	Business Operations		
Time Cap Laboratories, Inc.		037052099	manufacture(17714-122)		

Revised: 10/2017 Advance Pharmaceutical Inc.