SENNA- sennosides 8.6 mg tablets tablet AACE PHARMACEUTICALS, INC.

SPL UNCLASSIFIED SECTION

Senna Tablets

Sennosides 8.6 mg

AACE Pharmaceuticals, 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.

ACTIVE INGREDIENT (IN EACH TABLET)

Sennosides 8.6 mg

PURPOSE

Laxative

USES

- relieves occasional constipation (irregularity)
- this product generally produces a bowel movement in 6 to 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

age	starting dosage	maximum dosage
adults and children 12 years of age or older	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 docto

OTHER INFORMATION

- each tablet contains: calcium 4 mg, sodium 3 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

INACTIVE INGREDIENTS

colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, stearic acid

PRINCIPAL DISPLAY PANEL

†Compare to the active ingredient in Senokot®

Senna Tablets

Sennosides 8.6 mg

Natural Vegetable Laxative

Gentle, Overnight Relief of Constipation

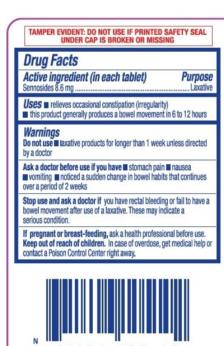
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

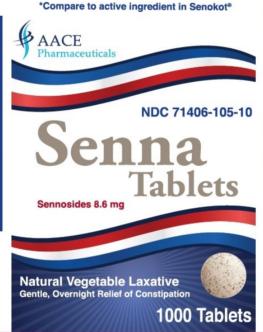
Manufactured by:

AACE Pharmaceuticals, Inc. Fairfield, NJ 07004

aacepharma.com

†This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Senokot®.







Other information = each tablet contains: calcium 4 mg, sodium 3 mg store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose

Distributed by: AACE Pharmaceutic Fairfield, NJ 07004

aacepharma.com Made in USA Rev. 01

*This product is not manufactured or distributed by Purdue Products L.P., owner of the registered tradmark Senokot®

Unvarnished LOT and EXP AREA





*Compare to active ingredient in Senokot®

Drug Facts (continued) **Directions** ■ Take preferably at bedtime or as directed by a doctor starting dosage 2 tablets 4 tablets adults and children 12 years of age or older twice a day once a day children 6 to under 12 years 1 tablet 2 tablets twice a day once a day children 2 to under 6 years 1/2 tablet 1 tablet once a day twice a day children under 2 years ask a doctor Other information each tablet contains: calcium 4 mg, sodium 3 mg

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Inactive ingredients colloidal silicon dioxide, croscarmellose sodiun hypromellose, magnesium stearate, microcrystalline cellulose, stearic acid

Manufactured by: AACE Pharmaceuticals, Inc., Fairfield, NJ 07004 aacepharma.com L-101 Rev. 00 *This product is not manufactured or distributed by Purdue Products L.P., owner of the registered trademark Senokot

Unvarnished LOT and EXP AREA

SENNA

sennosides 8.6 mg tablets tablet

Product Information

HUMAN OTC DRUG NDC:71406-105 **Product Type** Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX) **SENNOSIDES** 8.6 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Ch	Product Characteristics			
Color	brown (Light brown to grey)	Score	score with uneven pieces	
Shape	ROUND	Size	9mm	
Flavor		Imprint Code	S5	
Contains				

Ш	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:71406- 105-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/30/2019	
	2	NDC:71406- 105-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/30/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M007	08/30/2019	

Labeler - AACE PHARMACEUTICALS, INC. (080630748)

Revised: 1/2024 AACE PHARMACEUTICALS, INC.