

SENNA- sennosides 8.6mg tablet
Safacor Health, LLC

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

Sennosides 8.6mg

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 one 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 could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) 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 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	½ 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 50mg
- Store at 20°C-25°C (68°F-77°F); excursions permitted between 15°-30°C (59°-86°F)

Inactive ingredients

croscarmellose sodium, dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide.

Principal Display Panel**Senna Tablet****Sennosides 8.6mg**

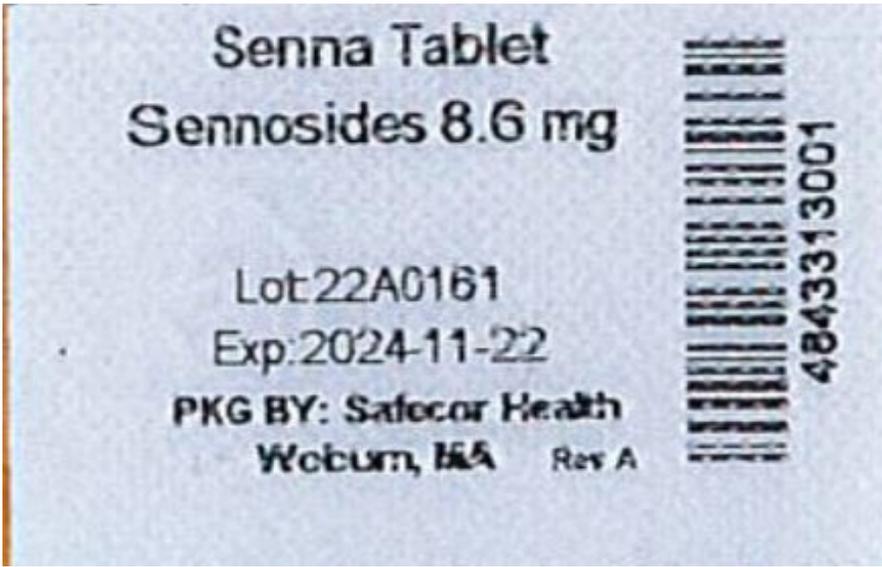
Lot: 22A0161

Exp: 2024-11-22

PKG BY: Safecor Health

Woburn, MA

Rev A



SENNA

sennosides 8.6mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48433-130(NDC:69168-371)
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	
Contains			

Packaging

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48433-130-01	100 in 1 BOX	12/01/2022	
1		1 in 1 BLISTER PACK; 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	12/01/2022	

Labeler - Safecor Health, LLC (828269675)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		078805287	repack(48433-130) , relabel(48433-130)

Revised: 12/2022

Safecor Health, LLC