

SENNA SYRUP- sennosides liquid
Safecor 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.

SAFECOR HEALTH

Senna Syrup (8.8 mg/5 mL)
Unit Dose Cup

Drug Facts

Active Ingredient (in each 5 mL = 1 teaspoonful)

Sennosides 8.8 mg

Purpose

Laxative

Use: • relieves occasional constipation (irregularity), generally causes bowel movement in 6-12 hours.

WARNINGS: Do not use • laxative products for a period 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 movement that continues over a period of 2 weeks

Stop use and ask a doctor if you have • rectal bleeding • no bowel movement after use of laxative

These could be signs of a serious condition.

If pregnant or breast feeding, ask a health care professional before use.

Keep this and all drugs out of reach of children. In case of overdose, get medical help or contact a Poison Control Center immediately. In case of eye contact, flush with water.

Directions:

- Shake well before use

- Do not exceed recommended dose

Age	Starting Dose	Maximum Dosage
Adults and children 12 years of age and over	2 to 3 teaspoonfuls (10 mL to 15 mL) once a day preferably at bedtime; increase as needed or as recommended by a doctor	3 teaspoonfuls (15 mL) in the morning and 3 teaspoonfuls (15 mL) at bedtime
Children under 12 years of age	Ask a doctor	Ask a doctor

1 teaspoonful = 5 mL

Other information: Store at room temperature 15°C to 25°C (59°F to 77°F). Excursions between 26°C to 30°C (78°F to 86°F) are allowed. Protect from excessive heat. For more info call 1- 800-447-1006.

Inactive ingredients: Artificial and natural chocolate flavor, methylparaben, propylparaben, propylene glycol, sucrose and purified water.

NDC: 48433-219-05 Senna Syrup 8.8 mg/5 mL Unit Dose Cup

Mfd. in the U.S.A.

Distributed by: Safecor Health, LLC

4060 Business Park Drive, Columbus, OH 43204

Rev: 02/2020 PN5497

———Principal Display Panel———

SAFECOR HEALTH

Senna Syrup

8.8 mg Sennosides per 5 mL

Contains 40 (5 mL) Unit Dose Cups

See monograph for complete drug information.

Store at room temperature 15°C to 25°C (59°F to 77°F);

excursions between 26°C to 30°C (78°F to 86°F) are allowed.

Protect from excessive heat.

This package design is not child resistant. For institutional use only.

Shake well before use.

NDC: 48433-219-40

Qty: 40

Lot: 20A0020

Exp: 210203

GTIN:

00348433219409

SN: 200600019

Pkg By: Safecor Health, LLC Columbus, OH 43204

Exp: 210203

Questions or Comments: Call 1-800-447-1006

Lot: 20A0020

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GTIN: 00348433219409

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Exp: 210203

Lot: 20A0020

PN5688.U



SENNA SYRUP

sennosides liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:48433-219(NDC:54859-808)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SENNOSIDES (UNII: 3FYP5M0JJX) (SENNOSIDES - UNII:3FYP5M0JJX)	SENNOSIDES	8.8 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SUCROSE (UNII: C151H8M554)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48433-219-40	40 in 1 BOX	03/01/2020	
1	NDC:48433-219-05	5 mL in 1 CUP, UNIT-DOSE; 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	03/01/2020	

Labeler - Safecor Health, LLC (828269675)

Establishment

Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	repack(48433-219)

Establishment

Name	Address	ID/FEI	Business Operations
Llorens Pharmaceutical International Division, Inc.		037342305	manufacture(48433-219)

Revised: 8/2023

Safecor Health, LLC