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 (26.4 mg/15 mL) Unit Dose Cup

Drug Facts

Active Ingredient (in each 15 mL = 3 teaspoonful) Sennosides 26.4 mg

<u>Purpose</u>

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	Dose
Adults and children 12 years of age and	15 - 30 mL up to 2 times a day
over	
Children under 12 years of age	Ask a doctor

3 teaspoon = 15 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: 48433-222-15 Senna Syrup 26.4 mg/15 mL Unit Dose Cup

NDC: 48433-222-40 Box of 40 Unit-Dose Cups, each unit-dose cup delivers

NDC: 48433-222-40

GTIN:

15 mL

For Oral Use Only. For Institutional Use Only. This Package Is Not Child Resistant.

Packaged By: Safecor Health, LLC 4060 Business Park Drive Columbus, OH 43204 05/2023 PN5737

———Principal Display Panel Box Label———

SAFECOR HEALTH

 Senna Syrup
 Qty: 40

 26.4 mg Sennosides per 15 mL
 Lot: 23A0081

 Contains 40 (15 mL) Unit Dose Cups
 Exp: 2025-07-31

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.

00348433219409

SN: 233000041
Pkg By: Safecor Health, LLC Columbus, OH 43204
Ouestions or Comments: Call 1-800-447-1006

SN: 233000041
Exp: 2025-07-31
Lot: 23A0081

-Principal Display Panel Unit Dose Cup Label———

Delivers 15 mL

NDC 48433-222-15

Senna Syrup

Each 15 mL Contains:

Sennosides 26.4 mg

SHAKE WELL

348433222157

Pkg By: Safecor Health, LLC

Columbus, OH 43204

PN5923.A

SAFECOR

Senna Syrup 26.4 mg Sennosides per 15 mL

Contains 40 (15 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.

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

Shake well before use



Pkg By: Safecor Health, LLC Columbus, OH 43204 Questions or Comments: Call 1-800-447-1006

NDC: 48433-222-40

Qty: 40 Lot 23A0081

Exp: 2025-07-31

Protect from excessive heat.

GTIN: 00348433222409 SN: 233000041 Exp: 2025-07-31

Lot 23A0081

SAFECOR

Senna Syrup 26.4 mg Sennosides per 15 mL

Contains 40 (15 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



Pkg By: Safecor Health, LLC Columbus, OH 43204 Questions or Comments: Call 1-800-447-1006



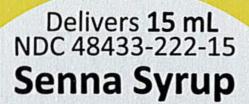
Qty: 40

Lot 23A0081

Exp: 2025-07-31

GTIN: 00348433222409 SN: 233000041 Exp: 2025-07-31 Lot 23A0081

NDC: 48433-222-40



Each 15 mL Contains: Sennosides 26.4 mg SHAKE WELL



348433222157

Pkg By: Safecor Health, LLC Columbus, OH 43204 N5923.A

SENNA SYRUP

sennosides liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:48433-222(NDC:54859-808)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength
ı			1

SENNOSIDES (UNII: 3FYP5M0IJX) (SENNOSIDES - UNII:3FYP5M0IJX) SENNOSIDES 8.8 mg in 5 mL

Inactive In	ıgredients
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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- 222-40	40 in 1 BOX	08/07/2023		
1	NDC:48433- 222-15	15 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	08/07/2023	

Labeler - Safecor Health, LLC (828269675)

Establishment			
Name	Address	ID/FEI	Business Operations
Safecor Health, LLC		828269675	repack(48433-222)

Establishment				
Name	Address	ID/FEI	Business Operations	
Llorens Pharmaceutical International Division, Inc.		037342305	manufacture(48433-222)	

Revised: 8/2023 Safecor Health, LLC