SENNA- sennosides a and b liquid ATLANTIC BIOLOGICALS CORP.

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 SYRUP

Active Ingredient

Active ingredient (in each 5 ml) purpose Sennosides 8.8 mgLaxative

Uses

relieves occasional constipation (irregularity) generally causes bowel movement in 6 to 12 hours

Directions

shake well before use take preferably at bedtime or as directed by a doctor

Age Starting Dose Maximum Dose adults and children 12 years 2 - 3 teaspoonfuls 3 teaspoonfuls twice a day

and older once a day

6 years to under 12 years of age $1 - 1\frac{1}{2}$ teaspoonfuls once a day $1\frac{1}{2}$ teaspoonfuls twice a day

2 to under 6 years of age ½ - ¾ teaspoon once a day ¾ teaspoon once a day

under 2 years of age consult a doctor consult a doctor

Warnings

Do Not Use • laxative products for longer than 1 week unless directed by a doctor Ask a doctor or pharmacist before use if you have

• stomach pain • nausea • vomiting

• notice 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 or failure to have a bowel movement after use of laxative. These may indicate a serious condition If pregnant or breast-feeding, ask a health professional before use

Inactive Ingredient

Flavors, parabens, propylene gylcol, sucrose and water Store at room temperature 15°-30°C (59°-86°F)

KEEP OUT OF REACH OF CHILDREN SECTION

KEEP OUT OF REACH OF CHILDREN SECTION In case of accidental overdose, get medical help or contact a Poison Control Center immediately

NDC 17856-1107-01 SENNA SYRUP

Natural Vegetable Laxative

17.6 mg Sennosides per 10 mL

For Gentle, Relief of Constipation

Unit Dose 10 mL Cup

Compare to active ingredient in Senokot®

PACKAGING INFORMATION:

Dosage per Cup: 10 mL Cup(s) per Case: 72

See package insert for Drug Facts

Other information:

Store at room temperature 15°-30 °C (59°-86°F).

SHAKE WELL BEFORE USE

KEEP SENNA SYRUP AND ALL MEDICINES OUT OF THE REACH OF CHILDREN

Mfg by:

Geritrex Corp.

144 Kingsbridge Rd East Mt Vernon, NY 10550

Repackaged by: Unit Dose Solutions, Inc. Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp. 20101 N.E. 16th Place

Miami, FL 33179

*Retain box label and package insert for drug information.

Questions or Comments: Call 1-800-509-7592

Lot No: 111111

MFG Lot No: XXXXXXXX Exp Date: 00/00/0000

NDC 17856-1107-05

SENNA SYRUP

Natural Vegetable Laxative

8.8 mg Sennosides per 5 mL

For Gentle, Relief of Constipation

Unit Dose 5 mL Cup

Compare to active ingredient in Senokot®

PACKAGING INFORMATION:

Dosage per Cup: 5 mL Cup(s) per Case: 72

See package insert for Drug Facts

Other information:

Store at room temperature 15°-30 °C (59°-86°F).

SHAKE WELL BEFORE USE

KEEP SENNA SYRUP AND ALL MEDICINES OUT OF

THE REACH OF CHILDREN

Geritrex Corp. Mfg by:

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Questions or Comments: Call 1-800-509-7592

Lot No: 111111 MFG Lot No: XXXXXXXX Exp Date: 00/00/0000



SENNA

sennosides a and b liquid

Product Information

Product Type HUMAN OTC DRUG NDC:17856-1107(NDC:54162-007) Item Code (Source) Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SENNO SIDES A AND B (UNII: 1B5FPI42EN) (SENNO SIDES A AND B - UNII: 1B5FPI42EN)	SENNOSIDES A AND B	415.36 mg in 236 mL	

Inactive Ingredients			
Ingredient Name	Strength		
METHYLPARABEN (UNII: A218 C7H19 T)			
ISOPROPYLPARABEN (UNII: A6EOX47QK0)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SUCROSE (UNII: C151H8 M554)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	COFFEE (Flavor)	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	1	10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	10/04/2016	
2	NDC:17856-1107- 5	5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	10/04/2016	
3	NDC:17856-1107- 2	120 in 1 BOX, UNIT-DOSE	05/23/2019	
3		2.5 mL in 1 SYRINGE; Type 0: Not a Combination Product		
4	NDC:17856-1107-3	48 in 1 BOX, UNIT-DOSE	05/23/2019	
4		5 mL in 1 SYRINGE; 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	06/19/2012		

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment				
Name	Address	ID/FEI	Business Operations	
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-1107), repack(17856-1107)	

Revised: 5/2019 ATLANTIC BIOLOGICALS CORP.