ONELAX SENNA- senna syrup ATLANTIC BIOLOGICALS CORP.

OneLAX SENNA SYRUP

Natural Vegitable Lexative Natural Choclate Flavor

Active Ingredient

| Active ingredient (in each teaspo | oonful) Purpose |
|-----------------------------------|------------------------|
| Sennosides 8.8 mg | Laxative |

Uses

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

Warnings

ask a doctor before use if you have • stomach pain • nausea • vomiting • noticed a sudden change in bowel movements that continues over a period of 2 weeks

Do not use laxative products for longer than 1 week unless directed by a doctor

Ask a doctor or pharmacist before use if

you are taking any other drug. Take this product two more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if

you have rectal bleeding or fail to have bowel movement after use of laxative. This 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. Shake Well Before Using.

| age | starting dose | maximum dosage |
|--|---|--------------------------|
| Adults and children 12 yeart and older | 2-3 teaspoons once a day | 3 teaspoons twice a day |
| Children 6 years to under 12 yeart | $1 - 1^{1/2}$ teaspoons once a day | day |
| Children 2 years to under 6 yeart | $^{1/2}$ - $^{3/4}$ teaspoon once a day | 3/4 teaspoon twice a day |
| Children under 2 years | ask a doctor | ask a doctor |

Other Information

• Avoid accessive heat. Store at room temperature 15°-30°C (59°-86°F)

Inactive Ingredients

flavor choclate, mythylparaben, propylene glycol, propylparaben, purified water and sucrose

KEEP OUT OF REACH OF CHILDREN SECTION

In case of accidental overdose, get medical help or contact a Poison Control Center immediately

Questions?

To Report Adverse Drug Event Call 1(877) 225-6999

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

MIAMI, FL 33179

17856-1127-01 SENNA SYRUP (SENNOSIDES) 8.8 mg PER 5 mL DELIVERS 4.4mg/2.5mL



See package insert for indications and dosage schedule

Natural Chocolate Flavored Vegtable Laxative. Shake Well Before Using. Store at Room Temperature 15°-30°C(59°-86°F). Avoid Excessive Heat.

Keep this and all Medications out of the reach of children



17856-1127-01 Dosage 4.4mg/2.5mL

SENNA SYRUP (SENNOSIDES)

GTIN: 00117856112716

S/N: XXXXXXXXXXX

Exp: 03/04/24

Lot: XXXXXXXXXX

Qty: 120 SYRINGES



Packaged by:

Distributed by: Atlantic Biologicals Corp. Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-1127-03 SENNA SYRUP (SENNOSIDES) 8.8 mg PER 5 mL DELIVERS 17.6mg/10mL



See package insert for indications and dosage schedule

Natural Chocolate Flavored Vegtable Laxative. Shake Well Before Using. Store at Room Temperature 15°-30°C(59°-86°F). Avoid Excessive Heat.

Keep this and all Medications out of the reach of children



17856-1127-03

Dosage 17.6mg/10mL

SENNA SYRUP

Qty: 72 CUPS

(SENNOSIDES)

GTIN: 0117856112731 S/N: XXXXXXXXXXX

Exp: 03/04/24

Lot: XXXXXXXXXX

Packaged by:

Distributed by: Atlantic Biologicals Corp. Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-1127-04 SENNA SYRUP (SENNOSIDES) 8.8 mg PER 5 mL DELIVERS 26.4mg/15mL



See package insert for indications and dosage schedule

Natural Chocolate Flavored Vegtable Laxative. Shake Well Before Using. Store at Room Temperature 15°-30°C(59°-86°F). Avoid Excessive Heat.

Keep this and all Medications out of the reach of children



17856-1127-04 Dosage 26.4mg/15mL

SENNA SYRUP (SENNOSIDES)

Qty: 72 CUPS

GTIN: 00117856112747

S/N: XXXXXXXXXXX

Exp: 03/04/24

Lot: XXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp. Miami, FL 33179

Rev.08/21

Call to Reorder:

ONELAX SENNA

senna syrup

| _ | | | |
|------|-------|--------|---------|
| Droc | 11164 | Inform | STIAN |
| PIUL | IULL | | Ialivii |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:17856-1127(NDC:71399-0027)

Route of Administration ORAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------|------------------------|
| SENNOSIDES A AND B (UNII: 1B5FPI42EN) (SENNOSIDES A AND B - UNII:1B5FPI42EN) | SENNOSIDES A AND B | 417.12 mg in 237 mL |

| Inactive Ingredients | | | |
|-------------------------------------|----------|--|--|
| Ingredient Name | Strength | | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | |
| PROPYLPARABEN (UNII: Z8IX2SC10H) | | | |
| WATER (UNII: 059QF0KO0R) | | | |
| SUCROSE (UNII: C151H8M554) | | | |

| Product Characteristics | | | |
|-------------------------|-----------|--------------|--|
| Color | | Score | |
| Shape | | Size | |
| Flavor | CHOCOLATE | Imprint Code | |
| Contains | | | |

| P | Packaging | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:17856- 1127-1 | 120 in 1 BOX, UNIT-DOSE | 03/05/2024 | | |
| 1 | NDC:17856- 1127-5 | 2.5 mL in 1 SYRINGE; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) | | | |
| 2 | NDC:17856- 1127-2 | 72 in 1 BOX, UNIT-DOSE | 03/05/2024 | | |
| 2 | NDC:17856- 1127-6 | 5 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product | | | |
| 3 | NDC:17856- 1127-3 | 72 in 1 BOX, UNIT-DOSE | 03/05/2024 | | |
| 3 | NDC:17856- 1127-7 | 10 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product | | | |
| 4 | NDC:17856- 1127-4 | 72 in 1 BOX, UNIT-DOSE | 03/05/2024 | | |
| 4 | NDC:17856- 1127-8 | 15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product | | | |

| Marketing Information | | | |
|---|------|-------------------------|-----------------------|
| Marketing Application Number or Monograph Category Citation | | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug | M007 | 02/06/2024 | |
| | | | |

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Registrant - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------|---------|-----------|----------------------------|
| UNIT DOSE SOLUTION | | 360804194 | repack(17856-1127) |

Revised: 3/2024 ATLANTIC BIOLOGICALS CORP.